Grant Agreement no. 287596

d-LIVER

ICT-enabled, cellular artificial liver system incorporating personalized patient management and support

INSTRUMENT: Collaborative Project (Integrating Project)

OBJECTIVE: ICT-2011.5.1

D6.2: Portable Data Logger

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PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including Commission Services)	
CO	Confidential, only for members of the consortium (including Commission Services)	

Document History

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1. Executive Summary

The d-LIVER project will develop a system for more efficient management of end-stage liver disease patients. One important aspect of this approach is to provide patients with home sensor devices in order to monitor their health and the need for any changes in the way care is given. A wearable physiological monitoring device is part of this, and the development of this component is described in the current deliverable. The wearable device is a portable data logger that is designed to collect sensory information as a basis to extract information on the physiological parameters of heart rate, activity, posture, skin temperature and blood pressure changes. The device is battery driven, and can be used by the patient during his or her normal daily routine. The data logger communicates with the d-LIVER Liver Patient Management System (LPMS) using Bluetooth (HDP protocol). The device is currently in the final stages of hardware realization, and will later be tested on liver patients within the framework of the project.

2. Introduction

2.1. Document scope

The deliverable outlines the functionalities of the d-LIVER Wearable Device, which is a system intended to be used by chronic liver failure patients for monitoring their vital signs. The objective is to measure continuously heart rate, skin temperature and activity parameters, as well as blood pressure changes, and thus provide information to the d-LIVER Liver Patient Management System (LPMS) that can support health professionals in their patient status assessment.

The work presented is the result of sensor development work carried out in WP3 (Task 3.1) and instrument platform integration work carried out in WP6 (Task 6.2).

The scope of the current report is to describe targeted design and functionality characteristics of the wearable device. In the next project period, work on verification and optimization of the sensor device performance will be carried out. Later in the project, the wearable device will be tested by liver patients in evaluation studies performed by the project's clinical partners.

2.2. Document audience

The document is public. Some familiarity by the reader with biomedical engineering in general and physiological monitoring in particular is assumed. As only a brief introduction to the overall d-LIVER system is given, the reader may also benefit from reading other d-LIVER reports, particularly the documents cited in Section 2.4.

2.3. Document structure

Introduction and scope is covered in the present section. Section 3 introduces the background and the targeted measurement concepts. Section 5 discusses how all the wearable device functionalities will be integrated into a functional unit.

2.4. Associated Documents

The d-LIVER project website (www.d-liver.eu) offers a good introductory description of the project objectives. Special reference is given to the "Public Deliverables" section of this website, where the documents cited in
Table 1 are of particular relevance to the wearable device.

Table 1: Public d-LIVER deliverables offering further background on the wearable device.

No:	Title	Wearable device relevance
D1.1	Specification of the clinical requirements for d-LIVER support	Provides the clinical basis for needs and requirements concerning wearable physiological monitoring
D6.1	Acceptance criteria of the d-LIVER system	Defines functional acceptance criteria for the wearable device
D7.1	Specification of the Overall Data Communication Architecture and Security Framework	Outlines how the wearable device will be used as a component in the d-LIVER liver patient management system.

3. Background and concept

3.1. The wearable device as part of the liver patient management system

The overall d-LIVER LPMS architectural view is shown in *Figure 1*. The wearable device will be one source of information in the LPMS, and specifically targeting the continuous collection of user vital signs (heart rate, activity parameters, skin temperature and blood pressure change indications).

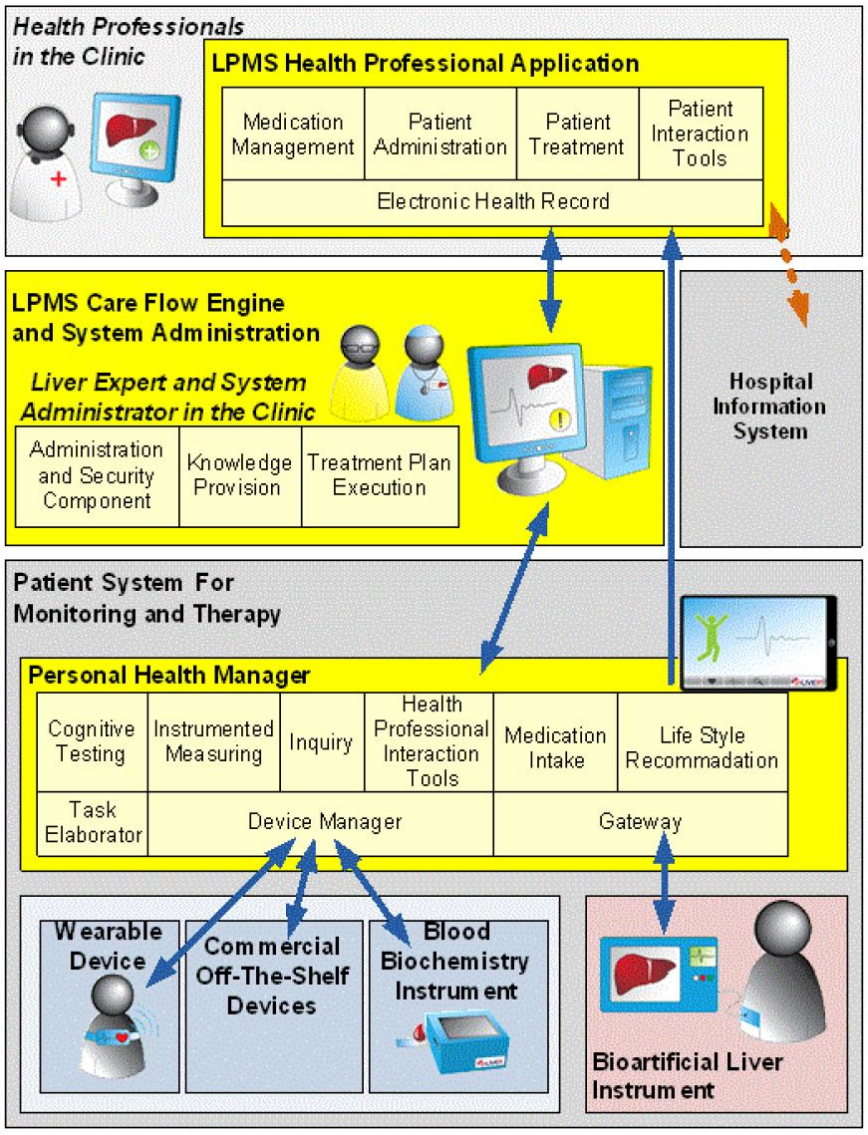

Figure 1: d-LIVER Liver patient management system component and interface architecture.

The wearable device will primarily be used by the patient in their own home. In the home, the patient will also have a blood biochemistry instrument capable of analysing 8 blood parameters on a daily basis from one droplet of finger prick blood. Further, the patient will use a number of additional physiological monitoring devices for intermittent use. These include weight scale, blood oxygen saturation and cuff-based blood pressure monitors. All these devices will be linked with the personal health manager via a patient touch screen user interface application. In addition, the patient will interact with the LPMS in a number of other ways using the personal health manager, including patient subjective feedback, cognitive skills analysis applications as well as the capability for voice and video communication with the health professionals.

3.2. Wearable Device Usage Scenarios and Functionalities

Home monitoring will be used in d–LIVER to detect changes in liver function and patient health status at an early stage, and may thereby enable the liver expert to make appropriate changes to therapy in order to avoid further deterioration. The combination of blood biochemistry measurements and "vital signs" measurements offer a "virtual bridge" for the doctor into the patient's home on a daily basis.

Truly continuous vital signs monitoring on a sustained basis (all day, every day) is only needed for a very few patients, typically belonging to intensive care patient groups, and therefore hardly suitable for home monitoring. Other patient groups can benefit from using continuous measurements during shorter time sequences (days-weeks-months); typically for monitoring the effects of medical interventions. These interventions can for example be grouped as follows:

1. Start a new treatment programme (such as d–LIVER enrolment).
2. Lifestyle change, outcome assessment and patient motivational tool (lifestyle changes such as exercise, substance abuse, diet, etc.).
3. Assessment of effect of medication adjustments.
4. Monitoring requested by medical personnel for patient status assessment.

Regarding the use of the wearable device in d–LIVER, a likely scenario is to use it extensively during the first month or so after d–LIVER enrolment in order to establish a patient base line. This time span will also help the patient to learn more about their own physiology (thereby contributing to patient empowerment), and it may also be possible to see the effect of, for example, changes in activity/exercise. Following this introductory use of the wearable device, we further expect that the device will be valuable for less frequent measurements, *e.g.* once a week, on a prolonged basis to ensure that values stay or move into an acceptable range. It may also be valuable to use the device more frequently during periods of therapy changes. Finally, the liver expert could request the patient to use the device for a certain time to evaluate the need for specific interventions.

The outline of the d–LIVER wearable device will include collection of the following sensory information:

- Electrodes for obtaining the following information:
    - heart rate
    - differential ECG trace
    - driving current and readout of impedance cardiography (ICG) measurements
- arterial pulse wave pattern extracted from optical plethysmograpic (PPG) measurements
- acceleration in three axis from an integrated MEMS accelerometer
- skin temperature using an infra-red (IR) temperature sensor

The combination of these sensor readings will allow simultaneous and quasi-continuous measurements of:

- heart rate
- pulse transit time – which varies with blood pressure
- skin temperature
- activity (reported in terms of steps, alternatively in terms of mean accelerations [m/s^2] over for example a one minute interval or as a categorization of activity level (high-medium-low))

- upper body posture

The term quasi-continuous is used because it will not be required to run all measurements all the time.

In addition to sensing functionalities, the device will have several other features, including:

- LED, vibrator and power button for user interaction
- On-board flash memory for intermediate data storage
- Li-ion polymer battery
- Micro-USB interface for charging and as device programming interface
- Bluetooth 2.1 communication, most likely employing an adaptation of the Health Device Profile

3.3. Wearable device system architecture

Figure 2 shows the wearable component architecture.

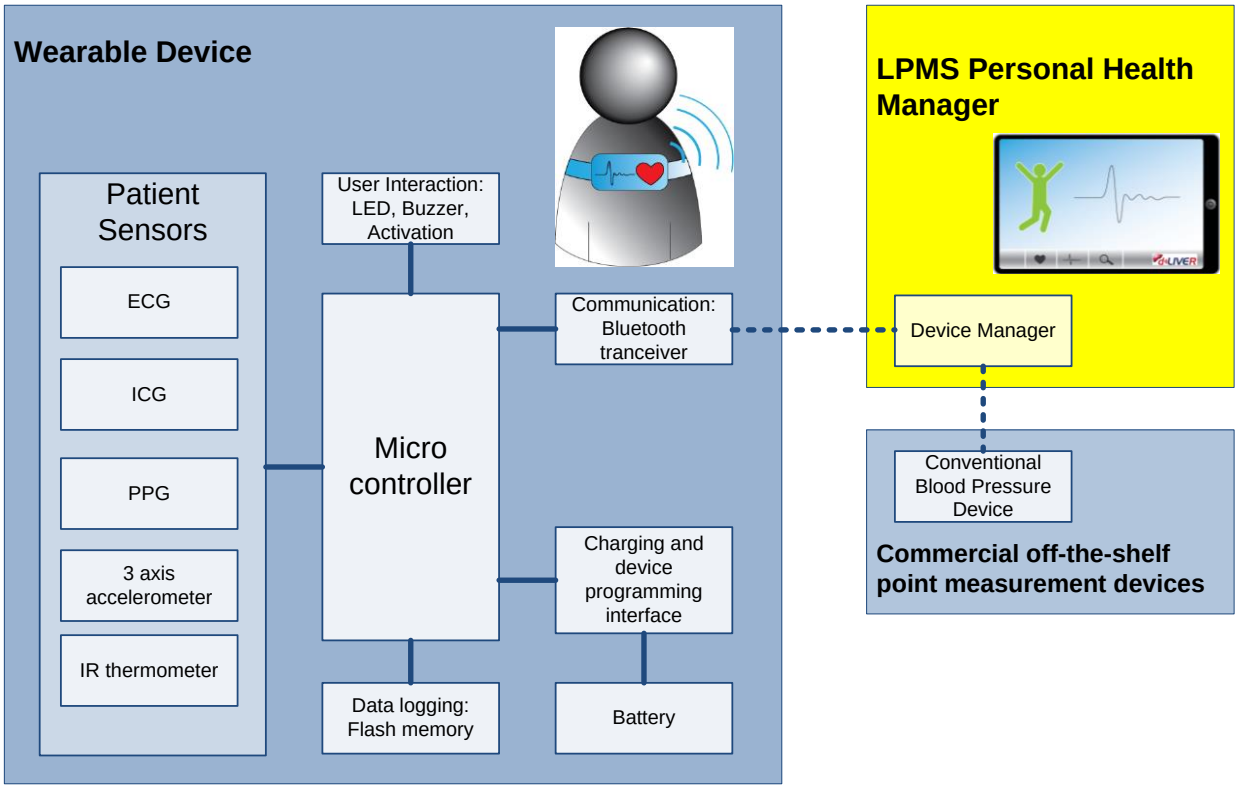

Figure 2: Architecture of the d-LIVER wearable device.

The data from the wearable device will be wireless transmitted using Bluetooth technology to the LPMS Personal Health Manager. Table 2 defines the values that will be forwarded from the wearable device to the personal health manager during typical patient use. The wearable device will not remain in continuous contact with the Personal Health Manager and hence the usage scenario will not include immediate alarm functionality, nor will continuous upload of measurements be targeted. On the contrary, the ambition is that the wearable device will work as a portable data logger that can collect and store physiological data for some time (several hours), and upload to the LPMS system when the user interacts with the system.

Table 2: Summary of parameters transmitted from the Wearable Device to the Personal Health Manager in normal patient use.

Parameter	Primary data source
Pulse transit time	Impedance cardiography and optical plethysmograpic measurements
Heart rate	ECG
Skin temperature	IR temperature sensor
Activity level	3-axis accelerometer
Posture	3-axis accelerometer
Number of steps	3-axis accelerometer

3.4. Medical Device Regulatory Aspects

The regulatory aspects concerning development and human subjects testing of medical device prototypes, as well as any future work to develop the prototypes into commercial products have been analyzed by the project. Whereas the medical device directives (e.g. Directive 93/42/EEC concerning medical devices) deal with requirements for legal marketing of medical devices, these directives add constraints that also affect the development phase of the project, and therefore can affect the ongoing d-LIVER project. Further, and even more important to d-LIVER, a certain level of directive compliance is required in order to carry out clinical investigations[1].

3.4.1. Medical Device Classification

An initial Medical Device Classification Assessment for the d-LIVER Wearable Device has been done, based on the definitions in the medical device directive (Directive 93/42/EEC) Annex IX and corresponding guidance documentation. The conclusion is that the wearable device should be considered as a Class IIa device. Another possibility was to design it as a Class I device by removing live data forwarding possibilities and by ensuring that it will not be used for direct diagnostic purposes. However, this approach would limit the device usage scenarios substantially.

3.4.2. Risk Management

The wearable device development process is subject to a structured risk assessment process. The purpose is to identify at an early stage any potential hazards and risks of adverse events to users, thereby making it possible to modify the device to remove or at least bring the risk level down to acceptable levels. The process is based on the ISO-14971 (2007) standard on medical device risk management, and is revisited and reviewed as the development progresses. The process initially identified 32 risk issues. Following review and conclusions on risk mitigation strategies possible, the risks could be reduced for a number of topics, and most importantly, for the issues classified as potentially of high (significant) risk items.

[1] Clinical investigation of medical devices for human subjects – Part 1: General requirements (EN ISO 14155-1:2011) and – Part 2: Clinical investigation plans (EN ISO 14155-2:2011)

4. Integration of sensor functionalities into a wearable device

4.1. Device design

The physical design of the wearable device is a trade-off between several design concerns. Aspects concerning the user interface, the comfort and ease of use have been highlighted in particular. However, all parameters concerning user safety, mechanics and functions as well as simplicity in assembly and prototype manufacturing were also taken into account.

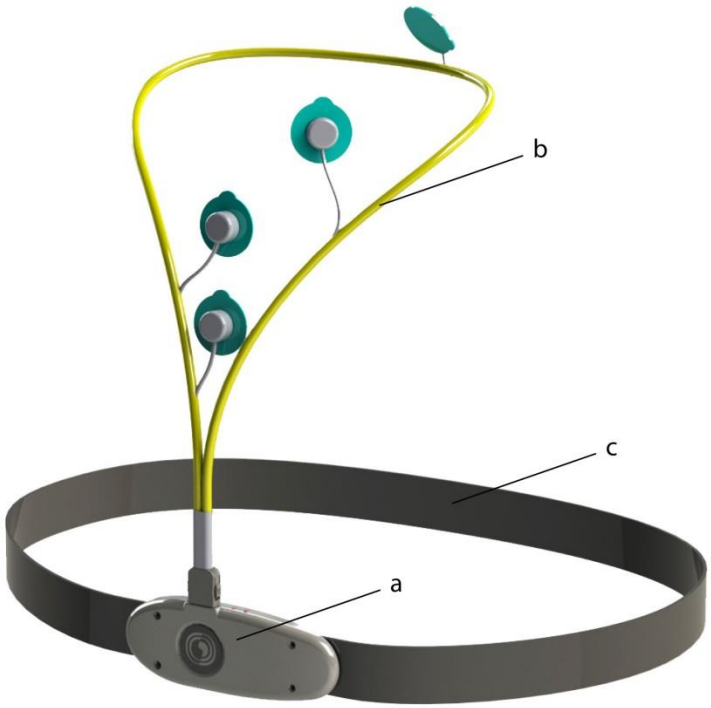

Figure 3: Wearable Device design with the main sensor compartment and data logger (a), neck harness (b) and chest belt (c).

The wearable device design is displayed in *Figure 3*. It consists of the following main items:

a. Main compartment containing the main printed circuit board with the microcontroller, Bluetooth module, flash memory, on-board sensors and sensor interfaces, as well as a battery and charger interface.
b. Neck strap with integrated electrodes for bio-impedance measurements employing ICG primarily. This strap is attached to the main compartment by an electrical contact, and thus provides sensor functionality, as well as weight support for the measurement compartment. For the purpose of the d-LIVER project, standard disposable electrodes will be chosen as they offer more design flexibility in an early stage.
c. A chest belt in an elastic fabric with two integrated electrodes. This component is easy to attach and remove by means of snap fasteners.

The device is designed to ensure that the electrodes and sensors are located correctly, and will allow easy adjustment to fit different sizes. Flexibility with respect to patient size is a pending issue, and it may be necessary to make several different sizes of the neck strap and chest belt.

The shell of the main compartment will be made in plastic and will protect the electronics from physical harm and humidity like sweat, but will not be made to tolerate soaking in water. The main compartment will be suitable for cleaning/disinfecting with chemicals like alcohols. It will be possible to detach the main compartment from the harness to wash the harness separately.

4.2. Device embedded firmware

4.2.1. Embedded software design

The embedded microcode software is written in standard C, using Cypress PSoC Creator and GNU GCC for compilation and debugging. The software is split into parallel tasks communicating with messages based on µC/OS-III RTOS functionality. The main control of the device is implemented with different states, as shown in Figure 4. Below follows a brief description of the states shown in the figure.

- *Start State* – Initializing
- *OffBody state* – device is not on body. After 5 minutes in this state without detecting that the harness has been put on, the wearable device will enter the stop state. No sensor data is stored in the device in the OffBody state.
- *OnBody state* – device is on body and sensor data is collected and stored.
- *Charging state* – charger is connected. Sensors are handled as for OffBody state.
- *Stop state* – power down and prepare for Standby state.
- *Standby state* – microcontroller is asleep. Interrupts are enabled to wake the microcontroller when the main button is pushed or the charger is connected. Minimum power is used in this state.

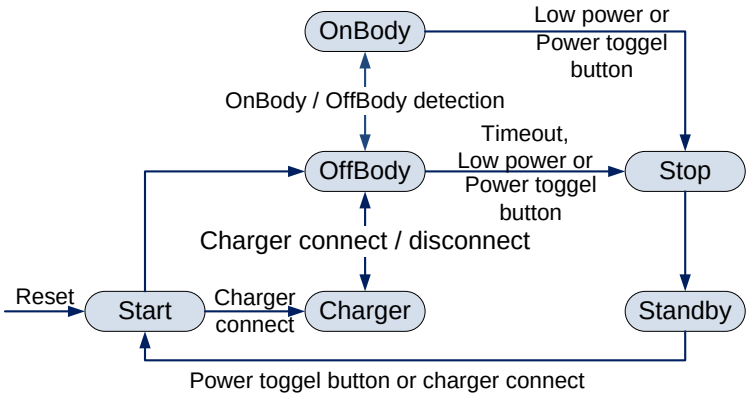

Figure 4: Embedded microcode software states of the controller.

4.3. Interface to LPMS

The wearable device communicates with the LPMS through a wireless connection using a Bluetooth 2.1 hardware module with a Health Device Profile (HDP), as shown in Figure 5.

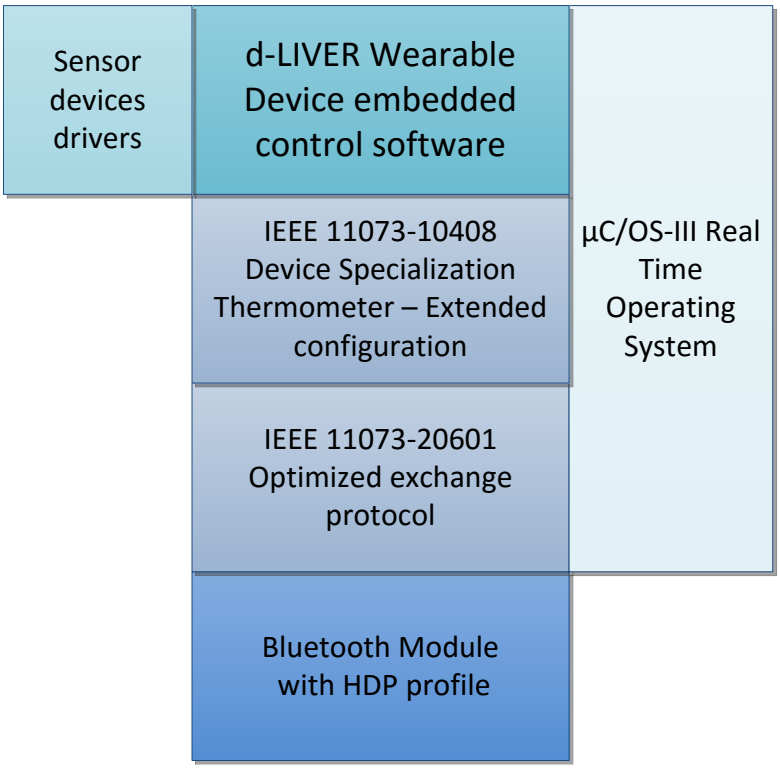

Figure 5: Embedded microcode modules.

The embedded microcode uses libraries to handle the IEEE 11073 set of standards. Sensor data is transmitted to the LPMS as an IEEE 11073-10408 Thermometer where the skin temperature is transmitted as standard data and the remaining data is transmitted as an extended configuration. The data transmitted is listed in *Table 2*. The sensor modules in the device are accessed via device drivers supporting the different sensors. µC/OS-III Real Time Operating System provides process, communication and timing functions used by the control firmware and IEEE 11073 modules.

5. Conclusions

The d-LIVER wearable device has been described. The wearable device is a portable data logger that can collect sensory information on the physiological parameters of liver patients. The objective is to collect information on heart rate, activity parameters, posture, skin temperature and blood pressure changes on a continuous basis. The wearable device is battery driven, and can be used by the patient while doing his or her normal life activities. It communicates with the d-LIVER liver patient management system using Bluetooth (HDP protocol). The device is currently in final stages of hardware realization, and will later be tested on liver patients by clinical partners within the framework of the project.