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Design of a wearable device for physiological parameter monitoring in a COVID setting

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***Abstract*— The study focuses on the realization of an accurate device for the detection of different physiological parameters. It has been realized a simple portable system containing the necessary electronics and ensuring the monitoring of the blood oxygenation, the body temperature, the air quality, the respiratory rate and the ECG. The main processing unit consists in a Raspberry Pi Zero W connected to the Healthy Pi4. The latter provides the interface for the clinical pulse-oxymeter while the measures of temperature and quality air are provided using the I2C protocol. The Bluetooth module is finally used to provide the ECG and blood rate data. The collected data are elaborated using Matlab and Python. To evaluate the accuracy of the realized device some experimental tests have been conducted on different subjects, comparing subjects working in Covid area with others resting at home. In both cases the monitoring time was 4 hours. Results have shown good performances of the system, detecting accurately the differences of the parameters values between the two situations. The usability of the device was assessed by administering a questionnaire to the healthcare personnel involved in the experimentation. The outcome shows a good usability of the system as well as an acceptable dressing time.**

***Index Terms*— Raspberry, COVID management, operator discomfort, monitoring.**

I. INTRODUCTION

The severe acute respiratory syndrome CoronaVirus-2 (SARS-Cov-2) is a new type of coronavirus that starting from the end of 2019 has spread from Wuhan to all over the world. COVID-19 is the name of the disease associated to this virus [1]. Collected data have demonstrated that this virus is transmitted among people through close contact and droplets. Therefore, the ones most at risk of infection are those in close contact with COVID-19 patients or that are caring for them [2].

Preventive and mitigation measures, such as sanitizing the hands frequently, have became crucial for all the community. Additional measures are required for healthcare workers to protect themselves and prevent the virus from spreading in an healthcare environment.

These include the appropriate use of personal protective equipment (PPE), besides administrative, environmental and technical controls [2], [3].

PPEs include N95 or KN95 respirators, corresponding to FFP2 or FFP3 in Europe, and single-used nitrile gloves to protect both the workers and patients health. Also, the health workers are clothed in impermeable suites and, because of the elevate virus transmittivity through mucous membranes, they wear eye protection such as goggles or face shield [3], [4].

The prolonged use of PPEs causes discomfort, especially for the intensive care unite (ICU) nurses, provoking complications [5] such as face and head pressure injures PIs due to the respirator or other face protective equipment. [4].

Considering also the great discomfort and the work-related stress our study is aimed at monitoring the physiological parameters of nurses on the COVID-19 ward at Careggi University Hospital (Florence). In this preliminary work we developed a simple portable device, and assessed its performance and easiness of use by acquiring and comparing measurements in a COVID settings with the ones acquired in a resting phase. Evaluating variations of the healthcare personnel parameters while wearing total barrier PPEs can lead to the realization of better protecting systems for the nurses and improve their ability to withstand stresses for longer periods of time.

II. MATERIALS AND METHODS

Blood oxygenation, body temperature, air quality (concentration of volatile organic compounds, VOCs, in the breath), respiratory rate, and ECG were monitored under both resting conditions at home and operating conditions inside a COVID-19 protection suit. Nurses wore a T-shirt with a pocket cut out at chest level, inside which the monitoring station was placed. The air quality sensor was applied to the FFP2 mask, the temperature sensor was attached to the body, while for the measurement of SPO_2 was used a sensor with an adhesive backing instead of the classic ”clothespin”, so as to avoid artifacts created by the presence of nitrile gloves. Respiratory Rate and ECG were monitored by using BioHarness Physiology Monitoring System (BIOPAC), attaching a module to a chest strap by insertion it into a custom receptacle. Details of the components of the system are reported below.

A. System architecture

The acquisition device consists of a custom-designed enclosure, containing all electronics (see Fig. 1), with connectors for the pulse-oxymeter, the temperature and air quality sensors, an on-off push button, and the recharge plug.

The box includes a Raspberry Pi Zero W, constituting the main processing unit and storing all collected data. The Pi is connected with an HealthyPi v. 4, that provides a standard

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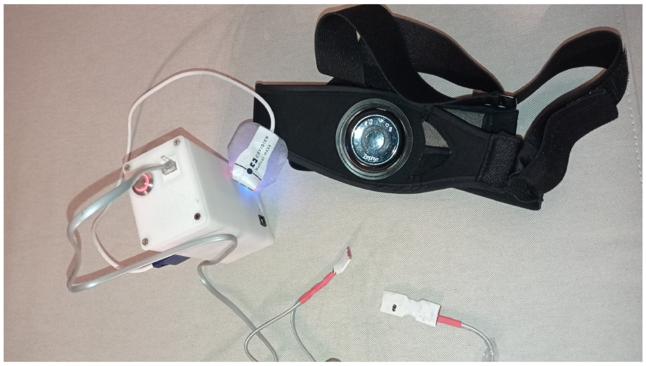

Fig. 1. Picture of the acquisition device, the Bioharness belt, air and temperature sensors and pulse-oxymeter

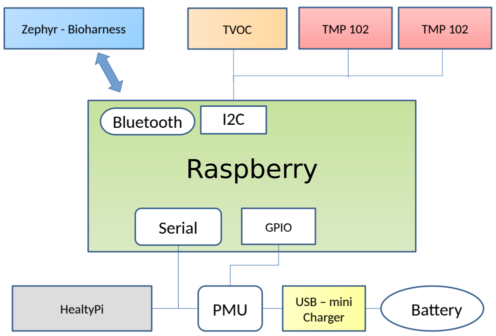

Fig. 2. HealthyPI-box communications diagram

interface for connecting a clinical pulse-oxymeter. Moreover, an I2C bus is used for installing a RTC, providing and accurate identification of the acquisitions, and for connecting with temperature and air quality sensors. Finally, a Bluetooth interface is used for connecting with a Biopac Bioharness belt, providing ECG and breath data.

Power is provided by a $4400\,\mathrm{mA}$ LiPo battery, connected with a standard battery booster/charger and a custom designed Power Management Unit (PMU). The resulting electronic layout of the connections is shown in Figure 2.

B. Power Management Unit

All commercially available LiPo booster/chargers provide a means for Raspberry to control their output (i.e. the Raspberry power supply), usually by means of the serial data out line; this limits the possibility to use the RS-232 port for communicating with the peripherals, in particular with the HealtyPi board. Moreover, the booster does not include any logic for an external on-off button. Therefore, we designed a custom PMU (Fig. 3, schematic available on request), with the same footprint of the Pi, providing: the possibility to enable the booster output with an additional GPIO pin, thus freeing the RS-232 communication; a on-off button, for turning on the device, or requesting shutdown; a led output for power status, with optional software control; two connectors for I2C bus and power (configurable at $3.3\,\mathrm{V}$ or $5\,\mathrm{V}$).

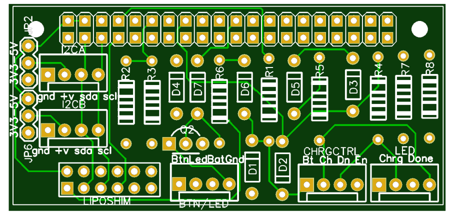

Fig. 3. Layout of the Power management unit

C. I2C bus

The I2C is a communication system using only a bidirectional data line (SDA) and serial clock line(SCL), in a master-slave configuration. The bus can be shared by up to 127 slaves with different addresses. In our design we included two connectors for I2C bus on the PMU, including two signal lines, power and ground.

The first connector is used for a DS1307 RTC module, located inside the device, and providing an absolute time reference (we cannot assume WiFi is available during all acquisitions, thus network time synchronization is not available) for acquired data. The second connector is used for external sensors, and is wired to a standard modular RJ11 plug.

D. HealthyPi

HealthyPi (v4 for this application) is an Hardware attached on Top, HAT, for Raspberry Pi, as well as a standalone device that can measure human vital signs that are useful in medical diagnosis and treatment [6]. HealthyPi v4 allows open source health solutions with mobility, wireless and wearable capabilities. It is able to measure several parameters in real-time, but in this work it has been used as interface only for the clinical pulse-oxymeter. This choice is related to the type of sensors chosen for the detention of the temperature and the air quality and the difficulty in connecting the ECG electrodes, placed under the vest, with the device without reducing the worker security.

E. Bioharness Physiology Monitoring System

The system operates in Bluetooth transmitting mode for real-time recording data. It consists of a module, that senses, records and transmits data, and an elastic band support inside which are stitched two electrodes, that must adhere to the chest. The module is attached to the band by inserting it into a custom receptacle.

Before wearing it, the user must wet the band sensing area with a little bit of water in order to improve its conductivity. The device uses sampling rates of $250\,\mathrm{Hz}$ and $25\,\mathrm{Hz}$ for heart rate and breathing rate, respectively [7].

F. Temperature sensors

The digital temperature sensor is a TMP102. It is featured by an accuracy of $0.5\,^{\circ}\mathrm{C}$ and it is powered at $3.3\,\mathrm{V}$. To obtain a better accuracy, manual calibration is still under experimentation. We used two sensors of the same type, configured with different I2C addresses, and located on the same bus.

G. Air quality sensor

Over certain range of Total Volatile Organic Compounds, TVOC, concentration, the likelihood of sensory effects (as irritation, dryness, weak inflammatory irritation in eyes, nose, airways and skin) increases. In our project, we included an Adafruit CCS811 Air Quality Sensor Breakout from AMS for air quality monitoring. This is a gas sensor that can detect a wide range of VOCs and is intended for indoor air quality monitoring. It returns a TVOC reading and the equivalent estimation of the concentration of carbon dioxide, (eCO2), using the I2C interface. The CCS811 has a 'standard' hot plate metal oxide, MOX, sensor, that measures the eCO2 concentration in a range from 400 to 8192 parts per million, (ppm), and the $TVOC$ concentration in a range from 0 to 1187 parts per billion, (ppb) [8].

H. Assembly of sensors

The monitoring station consists in a box that has been realized in ABS using the 3D printer. The internal structures of the box allow a reliable installation of all components in the minimum space. HealtyPi, Raspberry and the PMU are stacked on each other, while the RTC is fitted on the PMU. The box is designed to contain either a single charger/booster circuit, installed on the bottom cover, or separate booster (in particular a LipoShim) and charger circuits. In the latter case, the charger is still installed on the bottom cover, while the LipoShim can be directly connected to the PMU board.

External sensors, temperature and air quality, are installed on a single cable (about $1.5\,\mathrm{m}$ in length), equipped with a RJ11 plug. Because of the length of the cable, the speed of the I2C bus has been severely reduced, thus limiting the effect of capacitive losses on the cable. The first temperature sensor is installed with the air quality one in the far end of the cable; these two are designed to be installed inside the FFP2 mask, in order to monitor the the temperature (T_1) and the properties ($TVOC$) of the inspired and expired air. At the opposite, the second temperature sensor is placed about in the middle of the cable length and measures the body temperature (T_2).

The pulse-oxymeter probe Nellcor MAX-A (COVIDIEN) is a single-use probe, that is connected directly to the HealtyPi connector.

I. Data acquisition modules

The control software, written in python, is composed of four separate applications, saving data in different streams. This introduces some difficulties in the data synchronization, but allows each device to follow its specific timing, that is not user-defined.

The PMU control software is the software process that: monitors the battery status, allowing a clean shutdown when the battery is low; manages the on-off switch, powering off the device if the button is pressed for more than $5\,\mathrm{s}$; overrides the connection between RS-232 and the power control (the connection is required at boot time, as the RS-232 out bit is the only pin that has an high level when the central processing unit, CPU, starts the boot process).

The I2C bus master controls the acquisition of temperature sensors and the air quality one. It manages the connection with the I2C bus, acquiring both temperature and air quality values at a sample rate of 6 samples/minute, and saving them on a text file.

The HPi module records the raw data received from the HealtyPi on serial port that in turn is connected with the pulse-oxymeter. In this case, data are received in binary and saved in hexadecimal format, one packet for each line. The module checks the quality of data, in order to verify that the pulse-oximeter is properly connected and it is placed on the user finger. In case the device is not properly stuck to the skin, the amount of light received by the photodiodes saturates the input circuits; in this case, the power led flashes to indicate the warning condition.

The Bioharness module pairs with the Bioharness device using Bluetooth. Then a virtual serial port is used for polling the monitoring device and receiving both ECG and breath waveform. Again, data is received in binary format, thus it is stored in hexadecimal format, one data packet in each line.

All modules implement a safety mechanism for mitigate the risk of data loss; at regular intervals (presently, every minute), the output stream is closed and a new file is opened. In case of crash, including loss of power, only the last few seconds of data can be lost; moreover, the periodic splitting of the data files minimizes the synchronization errors during the processing phase.

III. Data-Processing

MatLab was used to process temperature and saturation readings, while the Python3 programming language was used for the heart rate and respiratory rate ones.

In both cases the hexadecimal data streams produced by the Healthy pi measurements and by the Bioharness module were processed and decoded, extracting the raw signal waveforms.

For the subsequent statistical analysis of the temperatures, the measurements were averaged over sub-intervals of 200 samples, thus eliminating those samples related to signal stabilisation.

IV. Acquisitions

In the present phase, we performed a small set of measurement for assessing the usability of the device, the reliability of the acquisition process and the quality of the resulting data.

The same equipment was tested on two different conditions: the first was a nurse male nurse working in the COVID-19 area of the Careggi Hospital, on whom recordings were made for 4 hours during night shifts with breaks of 10-20 minutes every 2 hours. The control set of measures corresponds to an adult male in a resting state at home. In both cases the monitoring time was 4 hours. Thus we obtained two different measurement conditions: the first one corresponding to the home environment, *Home*, where the subject is in a resting state and doesn't wear neither the suit neither the FFP2 mask (baseline situation); at the opposite the second condition corresponds to the Covid settings in the hospital, *Covid*, where the subject is working in the COVID-19 area, thus fully equipped with protective devices.

V. Results and Discussion

At the end of the experiments, questionnaires have been filled in by the health care personnel. They have highlighted the good usability of the device, both as concerns the amount of time required for wearing the sensors and the device, and for the discomfort caused by the device during work. In particular, time has been judged adequate, while the questionnaires report that the device caused almost no additional discomfort. It is lightweight and comfortably located on the chest without impairing movements. The same holds for the Bioharness monitoring system, that is usually intended for sport activities. The temperature and air quality sensors require careful placement of the cable in order to not hinder the user activities. Only the pulse-oxymeter, fitted under the glove, caused some additional discomfort to the user, requiring to be placed on the left hand for right-sided subjects.

The quality of the collected data is good and no major artifacts were present in the signals.

A preliminary evaluation has been carried out on the acquired data for checking the capability of detecting differences between different experimental conditions.

First results can be seen from the box plots in Fig. 4. The temperature T_1 is on average higher in Covid setting, when the subject is equipped with protective devices including the mask, than during the resting state at home. Differently, the temperature T_2 shows an opposite trend, probably related with different room temperatures. Measured $TVOCs$ concentrations, reported in Fig. 5, show the increase in $TVOC$ correlated with the mask usage. Also, the breathing frequency is lower in COVID settings (Fig. 5), probably due to the deeper breathing while wearing the mask.

VI. Conclusions and Future Developments

The obtained results showed a good performance of the device. It is an accurate system that allows to monitor physiological parameters without either adding further discomfort to the user or increasing the risk for his safety. The collected data also demonstrated the system capacity to accurately detect different values in relation to different situations. The acquisition of a larger data set, involving different working conditions, and different protective devices, is ongoing, and it will support a more detailed analysis on their impact in different working conditions. The team is also developing a miniaturized version of the device to improve its usability and further reduce the discomfort that it introduces.

TABLE I

Average and standard values of temperature and air quality; * indicates statistically significant differencies

Parameter	Home	COVID	
T_1 [°C]	28.1 ± 2.8	33.3 ± 0.4	*
T_2 [°C]	31.3 ± 2.7	34.7 ± 0.5	*
TVOC [ppb]	140 ± 171	509 ± 3086	*
Breathe[Hz]	0.40 ± 0.18	0.39 ± 0.25	*

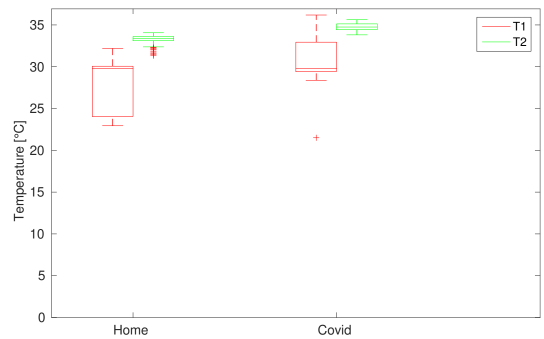

Fig. 4. Measured temperatures, for both sensors, in each experimental condition

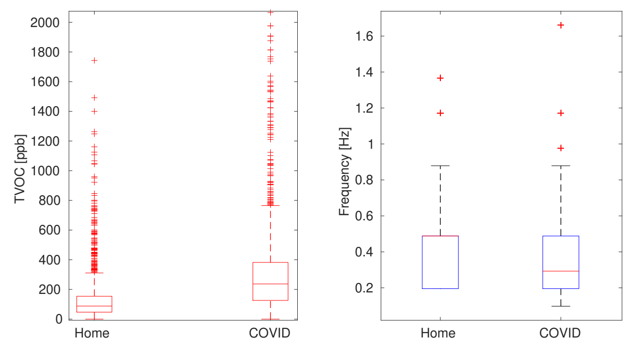

Fig. 5. TVOC (left) and breath frequency (right) comparison among resting state, without FFP2 mask, at home and in Covid area monitoring

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