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Design, implementation, and metrological characterization of a wearable, integrated AR-BCI hands-free system for health 4.0 monitoring

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ABSTRACT

An integrated real-time monitoring system based on Augmented Reality (AR) and Brain-Computer Interface (BCI) for hands-free acquisition and visualization of remote data is proposed. As a case study, the monitoring of patients' vitals in the operating room (OR) is considered; in particular, through the suitable combination of BCI and AR, the anesthetist can monitor in real-time (through a set of AR glasses), the patient's vitals acquired from the electromedical equipment. Healthcare-related applications are particularly demanding in terms of real-time requirements; hence, the considered scenario represents an interesting and challenging testbed for the proposed system. Experimental tests were carried out at the University Hospital Federico II (Naples, Italy), employing pieces of equipment that are generally available in the OR. After the preliminary functional validation, accuracy and delay were measured, demonstrating the effectiveness and reliability of the proposed AR-BCI-based monitoring system.

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1. Introduction

The use of the 4.0 enabling technologies is rapidly extend-¹⁵ ing also to other application contexts, such as finance, agri-¹⁶ culture, public administration, constructions, and healthcare ¹⁷ [1, 2]. In particular, information technologies such as the In-¹⁸ ternet of Things [3]; brain-computer interface (BCI) [4, 5]; ar-¹⁹ tificial intelligence [6, 7]; machine learning [8]; cloud comput-²⁰ ing [9]; additive manufacturing [10]; wearable sensors [11–14]; ²¹ as well as augmented, virtual, and mixed realities (AR, VR, & ²² MR) [15, 16] are fostering the digital transformation in health-²³ care. These technologies represent the pillars of medical cyber-²⁴ physical systems, which represent the most notable expression ²⁵

of the 4.0 Era, able to provide a more effective service and environment of healthcare [17–19]. Indeed, the health 4.0 paradigm is leaning towards a user-centered approach, with the aim to guarantee a flawless and natural interaction of the user with the technological systems, also resorting to novel computer/human interfaces such as BCI and AR.

BCIs can interpret human intentions through the analysis of the user's neuronal activity. BCIs can be considered as a powerful system to communicate with the external world [20], capable to create a direct link between man and computer. Originally, BCIs were mostly used as a communication means to support people with neurological disabilities [21]. However, in the last decade, the adoption of BCI has extended also to new application fields [22], such as gaming, entertainment, education, or robotics [23–26].

With regard to augmented reality, this technology overlays digitally-created content (often, in the form of images or text)

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to the surrounding reality, thus augmenting the user's percep- 87 30 tion of reality. Healthcare is benefiting from the technological 88 31 growth of AR, as this is being investigated for a number of med- 89 32 ical applications, such as preoperative surgical planning and im- 90 33 age guided surgery [27-31]. AR is also employed to display on 91 34 a set of wearable smart glasses the information related to the 92 35 patient's health (e.g., the electronic medical records or the pa- 93 36 tient's vitals acquired from the medical instrumentation). For 94 37 example, during surgical procedures, the anesthetist can access 95 38 the patient's information directly through the AR glasses, with- 96 39 out having to turn around and look at instrumentation [32-34]. 97 40 The adoption of AR glasses, in fact, can reduce by more than 98 41 one third the number of times the operator has to shift attention 99 42 from the patient to the equipment; as a result, the operator can₁₀₀ 43 intervene promptly in case of alert. 44

The suitable integration of AR with BCIs represents a 45 promising solution to achieve and improve a hands-free, 46 47 human-machine interaction [35]. Recent works, related to Industry 4.0 worker stress monitoring, and ADHD/ASD chil-48 dren rehabilitations [5, 36–38] have managed to overcome cost 49 and wearability issues [39], using off-the-shelf components and 50 single-channel systems. However, so far, the combination of 51 AR and BCI has not been addressed in a very critical applica-52 tion context, such as the medical one. Healthcare-related ap-53 plications are particularly demanding in terms of real-time re-54 quirements; hence, the considered scenario represents an inter-55 esting test-bed for the proposed AR-BCI system. 56

The typical requirements for AR applications include display 57 resolution, field of view, rendering capability, connectivity, 58 wearability, and latency [40]. In particular, latency is one of the 59 most critical: in fact, real-time applications generally require 60 maximum delays in the order of 75 ms for online gaming and 61 250 ms [41, 42] for telemetry, to prevent phenomenona such 62 as motion sickness. In the literature, a clinical assessment of a_{118}^{117} 63 real-time wireless transmission was carried out in [43], where 64 the transmission bandwidth, the number and the duration of the 65 stops, and the monitoring delay were analyzed to assess the 66 quality of the transmission. Also, in [44], the main challenges 67 related to mobile healthcare applications were explored, deal-68 ing with latency, reliability, bandwidth, energy efficiency, and 69 security. Results reported in [44] indicate that, to guarantee a $\frac{1}{125}$ 70 proper interaction between the user and the system, video/audio 71 delay should not exceed 300 ms. 72

On the basis of the aforementioned considerations, the case₁₂₈ 73 study considered in this work is a typical scenario during surgi-129 74 cal procedures, where the anesthetist has to monitor in real-time130 75 the patient's vitals. In such a context, a wearable BCI-AR sys-131 76 tem for real-time monitoring of patient's vitals is proposed and₁₃₂ 77 experimentally characterized. More specifically, a wearable,133 78 differential single-channel BCI based on Steady State Visually 134 79 Evoked Potentials (SSVEPs) is presented, wherein AR smart135 80 glasses are used for the generation of the flickering stimuli and 136 81 for displaying the patient's vital parameters coming from the137 82 medical equipment. Dry, noninvasive electrodes are used, to-138 83 gether with off-the-shelf components, to acquire and process the139 84 Electroencephalographic (EEG) signal. With respect to recent₁₄₀ 85 literature [5, 36, 45], in this work, also the possibility of using₁₄₁

four flickering stimuli instead of two is investigated, while preserving the single-channel configuration and at the same time, aiming to keep the current performance.

The present paper is organized as follows. Section 2 summarizes provides an overview of the theoretical background of BCI. In Section 3, the proposed monitoring system is described in detail, focusing both on the overall architecture and on the integration of AR and BCI. Section 4 addresses the implementation of the system: particular attention is dedicated to the AR-BCI hardware and to the communication between the devices. Section 5 presents the performance analysis of the implemented AR-BCI integrated system. Section 6 describes the experimental setup, the function validation and the metrological characterization of the monitoring system. Finally, in Section 7, conclusions are drawn.

2. BCI theoretical background

Brain signals can be captured by means of functional magnetic resonance (fMRI), magnetoencephalography (MEG), or near-infrared spectroscopy (NIRS). However, EEG is considered as the best choice for its non-invasiveness, time-response, high accuracy, usability and low cost [20, 46]. The most used BCI paradigms are (i) P300; (ii) SSVEPs; (iii) event-related potentials (ERPs); and (iv) sensorimotor rhythms (SMR).

In particular, SSVEPs and ERPs (event-related potentials) are potentials triggered by an event.

However, ERPs are endogenous [47] potentials: ERPs are triggered by the mental act of the subject; hence, they have higher latency as they involve stronger mental processes. For example, P300 is an ERP potential occurring 300 ms after a stimulus, and it is largely used in BCI speller application [48]. Sensorimotor rhythm are related to variations of power in the band 8-25 Hz, generated by the execution or the imagination of a movement of a part of the body [49].

On the other hand, SSVEPs are exogenous potentials [50], since the response is physiological and can be measured even after less than 100 ms. Compared to the aforementioned ERP signals, SSVEPs have a fixed frequency oscillation that allows easier detection, even when using fewer electrodes, or in more noisy conditions. SSVEPs [51–53] represent a promising choice for practical applications, as they achieve high levels of accuracy and reproducibility [51, 54, 55] without the need of training for the user [45, 56]. Additionally, the BCI-SSVEP paradigm guarantees an optimal trade-off between wearability and performance, ensuring low response times.

SSVEPs are induced in the primary visual cortex when observing intermittent visual stimuli [57]. For most of the subjects, a majority of signal energy lies within the band 8-15 Hz [51]. SSVEP signals have the same periodicity of the external stimuli and have been used in many applications in the last decade, from home appliances control to spelling systems, video-games, robots, quadcopters and prosthesis control [45, 58–62].

Extracting meaningful information from noisy SSVEP signals in reasonable time and with high precision (while preserving user comfort), is a major challenge: the main difficulties arise 200

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from the type of electrodes, which often require the applica-193 142 tion of specific solutions to improve the quality of the contact194 143 and, therefore, the signal-to-noise ratio (SNR). The number of 195 144 electrodes also contributes to signal identification, where the196 145 combined information increases the SNR, especially at short in-197 146 tervals. In [63], for example, a robotic arm has been controlled₁₉₈ 147 using a 10-channels SSVEP-based BCI reaching an accuracy of 199 148 92.78% and 4 s response time. 149 200

Different studies investigated the effects of stimuli properties₂₀₁ 150 on the brain response [64, 65]. In particular, it has been ob_{-202} 151 served that SSVEP power increases considerably with increas-203 152 ing contrast and decreasing distance of the user from the vi-204 153 sual stimuli. Moreover, the number of simultaneous stimuli and₂₀₅ 154 their inter-distance affect both the user's attention and the brain₂₀₆ 155 response. Hence, VR head-mounted display and AR glasses are207 156 optimal candidates for generating visual stimuli, since the im-157

ages of the flickering stimuli can be projected straight towards 158 the eyes, thus reducing the noise factors of the surrounding en-208 159 vironment. 160

210 3. Proposal 161 211

3.1. Basic ideas 162

As aforementioned, the present work proposes an integrated₂₁₄ 163 BCI-AR system, in which AR glasses are used 1) to monitor₂₁₅ 164 the patient's vitals acquired in real time from the medical in-216 165 strumentation, and 2) to render the visual stimuli for the BCI-217 166 SSVEP system. The brain-driven selection is used to navigate₂₁₈ 167 168 the AR menu, showing the patient's vital signs in real-time. 219 The proposed BCI-AR system operates as follows. The user₂₂₀ 169 wears the AR glasses and the EEG electrodes; the system re-221 170 ceives the patient's vitals from the operating room equipment, 171 and displays them in real time on the AR glasses. Through a₂₂₂ 172 BCI, the user can select which parameters they want to be dis-173 played. In the following section, the conceptual architecture₂₂₅ 174 and his described in detail. 175 224

3.2. Architecture 176

As shown in Fig. 1, the general architecture of the proposed 177 system includes three major blocks: 178

- The *Monitoring Equipment*; 226 179
- The Equipment Control Unit (ECU); and 180
- The AR-BCI Integrated System. 181

The expression Monitoring Equipment is used to indicate a231 182 generic set of measuring instruments, whose output data can be232 183 monitored in real time through the AR-BCI integrated system. 233 184

The AR-BCI subsystem allows the user to select which infor-234 185 mation, acquired from the Monitoring Equipment, he/she would235 186 like to be displayed in AR. More specifically, the AR Glasses236 187 render the flickering visual stimuli that are used to elicit the237 188 SSVEP in the user's brain. Each flickering visual stimulus is238 189 associated to one possible user's selection. 190

Then, the EEG Wearable Transducer (which includes the Elec-240 191 trodes and an Acquisition Unit), acquires and digitizes the EEG₂₄₁ 192

signal. This signal is elaborated by the *Processing Unit*, and the result is sent by the Wireless Transceiver to the ECU.

The ECU collects the data from the Monitoring Equipment. Once the data are received by the Data Collector unit, the ECU sends the output data (as selected by the user through the BCI) to display on the AR Glasses. This communication occurs by means of the Wireless Transceiver.

The ECU is also equipped with a Measurement System, which can assess the performance of the system. In particular, the quality of the transmission is assessed, expressed in terms of accuracy and latency for both data update and communication delay.

Finally, a Metrological Characterization feature is also included in the ECU, to report the results related to the quality of the transmission.

3.3. AR-BCI Integrated System

The AR-BCI Integrated System (Fig. 2) allows (i) the rendering of the visual stimuli for BCI-SSVEP, and (ii) the visualization in real time of the acquired parameters.

The highly-wearable BCI equipment includes EEG active dry *Electrodes* to acquire the EEG signal from the user scalp, and an Acquisition Unit to digitize the signal.

This BCI equipment, integrated with the AR Glasses, allows to select which data output to display among those available from the Monitoring Equipment. The result of the processing is sent by the Wireless Transceiver to the ECU, which collects the data from the instrumentation and sends them wirelessly to the AR Glasses, according to the user's selection. Overall, the AR/BCI platform includes:

- A *Processing Unit* to detect the observed stimulus;
- The AR glasses which provide the visual stimuli for the BCI and also the visual feedback; and
- The Wireless Transceiver for the communication.

3.3.1. EEG wearable transducer

The AR Glasses are used to generate the visual stimuli to elicit SSVEP response in the user's EEG [51]. Then, three electrodes, placed on the user scalp, are used to acquire the EEG signal in a single-channel differential measurement. As can be seen from Fig. 2, according to International 10-20 System [5, 36], brain signals are captured using two active electrodes positioned at the Frontal Midline (Fz) and Occipital Midline (Oz) positions, connected to the negative and positive input of the acquisition unit, respectively. A passive electrode, DRL (Driven Right Leg), is positioned on the earlobe and acts as a reference. The Fz and DRL electrodes contacts are gold-plated, flat surfaces, while the Oz electrode was modified by adding eight gold-plated spring connectors, to ensure a more effective skin contact through the hair. Signals acquired through the electrodes are digitized by the Acquisition Unit.



Fig. 1: Concept architecture of the proposed AR-BCI monitoring system.



Fig. 2: AR-BCI architecture based on the SSVEP paradigm.

242 3.3.2. SSVEP Processing

The *EEG Digitized Signal* is sent to the processing unit to provide the information received from the *Acquisition Unit*. The result of the processing is received by the *ECU* by means of the *Wireless Transceiver*: this step allows the user to see²⁴³ through the *AR Glasses* the information coming from the *Mon*-²⁴⁴ *itoring Equipment*.

Fig. 3 summarizes the SSVEP acquisition and processing. A²⁴⁵ correlation-based algorithm [36] is used to detect the frequency²⁴⁶ elicited by the observed stimulus. Given a time window of²⁴⁷ length *T*, the corresponding signal fragment is filtered using a²⁴⁸ band-pass finite impulse response (FIR) filter between 5 Hz and²⁴⁹ 25 Hz. Then, the filtered signal fragment is correlated with four²⁵⁰ sine waveforms Φ_i where i = 1, ..., 4. Each waveform has a fre-²⁵¹ quency corresponding to a flickering visual stimulus, and vari-²⁵² able phase ϕ , obtaining the maximum values among the Pearson²⁵³ correlation coefficients ρ_i where i = 1, ..., 4, as expressed by the²⁵⁴ following equation:

$$\rho_i = \max_{\phi \in [0,2\pi]} \frac{\operatorname{cov}(D_f, \Phi_i(\phi))}{\sigma_{D_f} \, \sigma_{\Phi_i(\phi)}} \tag{1}_{25}^{25}$$

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where D_f are the filtered Data; Φ_i represents the *i*th sinewave; ϕ is the phase; σ_D is the standard deviation of the filtered data; and σ_{Φ_i} is the standard deviation of the sinewaves. Hence, the following features are extracted:

$$F1 = \lim_{i \in [1,4]} \max(\rho_i)$$
(2)

$$F2 = 2^{nd} \max_{i \in [1,4]} (\rho_i)$$
(3)

$$F3 = \frac{F1 - F2}{F2} \tag{4}$$

where F1 represents the maximum value among the correlation coefficients for all the four frequencies; F2 is the second largest correlation coefficient corresponding to one of the remaining three frequencies of stimuli; and, finally, F3 represents the relative difference between F1 and F2.

Given any two threshold values *T1* and *T2*, a signal fragment can be marked as recognized if the following condition is satisfied:

$$F1 > T1 \quad \cap \quad F3 > T2. \tag{5}$$

If condition (5) is not satisfied, a new fragment of duration T, overlapping with the previous one by T/2, is processed.

3.4. Metrological characterization of the data transmission

An off-line feature for metrological characterization, related to the communication between the devices, is included in the AR-based system. The corresponding block of *Metrological Characterization* (as shown in Fig. 1) allows to assess (i) the transmission accuracy between the ECU and the Monitoring Equipment; (ii) the data-update delay; and (iii) the communication latency.

The data-update delay depends on the communication between the *Monitoring Equipment* and the *ECU*, while the communication latency refers to the communication between the *ECU* and the *AR-BCI Integrated System*, and depends on the communication protocol used. To this aim, different experimental sessions, each consisting of several runs, are carried out automatically.



Fig. 3: Workflow of the SSVEP acquisition and processing.

For each run, the transmission accuracy, A (%), is assessed₂₆₁ as: 262

$$A = \frac{N_{packets} - E}{N_{packets}} \cdot 100 \tag{6}_{26}^{26}$$

where $N_{packets}$ is the number of packets sent, and *E* is the error²⁶⁵ count when a packet is not correctly decoded.

Then, for each session, the accuracy mean value μ_A and the²⁶⁷ standard deviation σ_A are assessed. Hence, the 3-sigma uncer-²⁶⁸ tainty is computed, by taking into account the total number of²⁶⁹ runs, according to the following equation: ²⁷⁰

$$u_{\rm A} = \frac{k \cdot \sigma_{\rm A}}{\sqrt{N}} \tag{7}_{271}$$

where k = 3 is the coverage factor, corresponding to 99.7% con-²⁷² fidence interval, and *N* is the total number of runs.

After the accuracy evaluation, the time interval necessary to₂₇₅ update the data coming from the monitoring isntruments is mea-₂₇₆ sured. In particular, the time related to: (i) data-update, and (ii)₂₇₇ wireless communication is assessed for each packet sent within₂₇₈ a run. At the end of each run, the mean value and the standard₂₇₉ deviation of these quantities are evaluated. 280

Successively, at the end of the session, the weighted mean and₂₈₁ the 3-sigma uncertainty are assessed, considering the different₂₈₂ number of packets sent for each run, in order to give the best₂₈₃ estimate of the measurand. In particular, the weighted mean of₂₈₄ the time delay μ_t is evaluated through the following equation: ₂₈₅

$$\mu_{t} = \frac{\sum_{i=1}^{N} \mu_{ti} \cdot l_{i}}{\sum_{i=1}^{N} l_{i}}$$
(8)

where μ_{ti} is the mean of the time delay evaluated for each run;₂₉₀ and l_i is the number of packets for each run. The evaluation of₂₉₁ the 3-sigma uncertainty is carried out taking into account the law of propagation of uncertainty.

Assuming μ_t as the weighted mean among the runs, as defined by (8), the uncertainty is evaluated through the following equa-²⁹³ tion:

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$$u_{\rm tpr} = \sqrt{\sum_{i=1}^{N} \left(\frac{\partial \mu_t}{\partial \mu_{ti}} \cdot u_{ti}\right)^2} \tag{9}^{296}_{297}$$

where u_{tpr} is the 3-sigma uncertainty (assessed through (7)) of the time delay evaluated with the law of propagation of uncertainty, assuming the independence between each run (an hypothesis considered acceptable based on the previous experimental campaigns); and u_{ti} is the uncertainty of the time delay evaluated for each run.

When the metrological self-characterization of the system is completed, a metrological report, summarizing the (i) transmission accuracy, (ii) the data-update delay, and (iii) the communication latency is produced for the user.

4. Implementation

As mentioned in the introduction, for the implementation, a specific healthcare-related scenario was considered. In fact, the medical environment is generally very demanding in terms of real-time requirements; hence, it represents an optimal testbed for the proposed system. The proposed AR-BCI system was implemented to be used in the operating room, to allow the OR operators (and, in particular, the anesthetist) to monitor in real-time through AR glasses the patient's vitals acquired from the OR equipment. The user interacts with a BCI to select which vital parameters he/she wants to be displayed.

This section describes the implementation of the proposed system. In particular, more details are given about

(i) the *ECU*;(ii) the *OR Equipment*; and

(iii) the *AR-BCI Integrated System*, from the AR Glasses to the BCI Hardware.

The implementation of the system and the experimental tests were carried out at the Academic Hospital of Federico II University (Naples, Italy), employing monitoring equipment available in the operating room.

4.1. ECU

For the implementation of the system, a laptop was used as an *ECU*. The laptop has an AMD A10-9600P Processor, 16 GB RAM, and two USB 2.0 ports, which are used to communicate with the *OR Equipment* and the *AR-BCI Integrated System*. A WiFi technology *IEEE 802.11a/b/g/n* is also provided



Fig. 4: OR Equipment: a) Drager Evita Infinity V500 ventilator; b) Philips IntelliVue MP90 patient monitor.

for the wireless communication with the aforementioned sys-208 tem blocks. A software running in MATLAB environment col-299 lects the data from the OR Equipment, checks if any error has³³² 300 occurred, and sends the data to the AR-BCI Integrated System, 301 according to the user's selection. Moreover, the developed soft-302 ware provides a measurement of the transmission performance³³⁴ 303 335 in terms of accuracy, data update and communication delay. 304 336

305 4.2. OR equipment

For the implementation of the proposed system, two electromedical instruments were used, namely a ventilator for intensive care and a patient monitor: these are pieces of equipment that are typically available in the OR [37].

- Ventilator: Fig. 4(a) shows a picture of the mechanical³⁴³₃₄₄
 ventilator used for the implementation, namely the Drager³⁴⁵₃₄₅
 Evita Infinity V500 [66]. This ventilator is equipped with³⁴⁶₃₄₆
 a LAN interface and three serial interfaces, and it is possi-³⁴⁷₃₄₇
 ble to fetch the parameters using the MEDIBUS protocol³⁴⁸₃₄₈
 at different Baud Rates.
- Monitor: Fig. 4(b) shows the monitor used for the imple-⁵⁰⁰ mentation, namely the Philips IntelliVue MP90 [67]. Intel-³⁵¹ liVue MP90 has a conventional diagnostic 12-lead ECG,³⁵² arrhythmia, arterial blood pressure and oxygen saturation analysis. It is equipped with a LAN interface; data are³⁵³ collected by means of a dedicated proprietary software,³⁵⁴ namely *Medicollector*.

356 In this application, the vital signs coming from the instrumen-357 323 tation are collected by the laptop, which communicates (i) with₃₅₆ 324 the Ventilator over MEDIBUS protocol via RS-232 to USB 325 adapter, and (ii) with the Monitor via Medicollector adapter, a359 326 LAN to RS-232 adapter. To establish a LAN-USB connection₃₆₀ 327 between the patient monitor and the laptop, an additional RS-361 328 232 to USB adapter was used. The parameters acquired from₃₆₂ 329 the instruements are displayed in real-time on the AR glasses₃₆₃ 330 which receive wirelessly the data collected from the laptop. 331 364



Fig. 5: AR-BCI Equipment: a) Moverio BT-350; b) Olimex EEG-SMT; c) Raspberry Pi 3.

4.3. AR-BCI integrated system

The AR-BCI integrated system was implemented using components off-the-shelf. It includes

(i) a pair of AR Glasses;

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(ii) *Electrodes* and *Acquisition Unit*, constituting the *EEG Wearable Transducer* in Fig. 2; and

(iii) a Processing Unit, integrating the Wireless transceiver.

- *AR glasses*: In this work, the Epson Moverio BT-350 [68] glasses were used (Fig. 5(a)). This is an AR optical seethrough (OST) device with a 30 Hz nominal refresh rate; an angle of view of 23 degrees diagonally; and a *720p* display. These AR smart glasses are equipped with Android 5.1. A dedicated Android application was developed and built with a twofold aim: (i) for generating the flickering visual stimuli for the BCI-based input; and (ii) for receiving and displaying in real-time the vital signs from the OR equipment
- *Electrodes and Acquisition Unit:* the Olimex EEG-SMT was used as an Acquisition Unit [69], a 10-bit, 256 Sa/s, differential input Analog-Digital Converter (ADC). The electrodes and the Olimex are shown in Fig. 5(b).
- *Processing Unit:* This includes a Raspberry Pi 3 (Fig. 5(c) [70]), connected via USB to the Acquisition Unit. The Raspberry Pi 3 is also used as a *Wireless Transceiver*, to communicate the results of the SSVEP detection to the laptop. In this way, the user is capable to move smoothly in the OR thanks to the high wearability.

Overall, this configuration of the AR-BCI System represents a single-channel BCI, which guarantees:

(i) high wearability, thanks to the low number of EEG electrodes and the small dimensions of the hardware used, and(ii) high accuracy and low latency, even employing low-cost hardware.

365 4.4. Communication

Dedicated software was developed to handle (i) the communication between the laptop and the OR Equipment; (ii) the communication between the EEG Acquisition Unit and the EEG Processing Unit; (iii) the communication between the EEG Processing Unit and the laptop; and (iv) the communication between the laptop and the AR Smart Glasses. Fig. 6 describes in detail the communication between the devices.

(i) Communication between the laptop and the Equipment: A 373 code running in MATLAB environment was developed to im-374 plement the acquisition from the instrumentation and sending 375 of the data. A subsection of the MATLAB code implemented 376 the MEDIBUS protocol at a Baud rate of 38400 bit/s to con-377 figure and receive in real-time the ventilator parameters. Fur-378 thermore, a second subsection is in charge of exchanging data 379 with Medicollector (i.e., the proprietary softwaref for acquiring 380 the waveform from the monitor). While Medicollector is run-381 ning on the laptop, the MATLAB code acquire in real-time the 382 desired Monitor waveforms over TCP/IP protocol. 383

(ii) Communication between the EEG Acquisition Unit and 384 the EEG Processing Unit: The digitized EEG signal is sent via 385 USB to the EEG Processing Unit. The software installed on 386 the Processing Unit is written in C, and acquires via UART the₄₁₈ 387 EEG signal digitized by the Acquisition Unit. The Baud Rate 388 is set to 57600 bit/s, the packet size is equal to 17 bytes, and no₄₂₀ 389 parity bit is foreseen. The software also provides the function421 390 of TCP Client, sending to the laptop (acting as a TCP Server) 301 the result of the processing. 392 423

(iii) Communication between the EEG Processing Unit and 424 393 the laptop: For the laptop, a TCP Server was implemented and₄₂₅ 394 integrated in MATLAB with the code for the acquisition of the $_{426}$ 395 parameters from the OR equipment. The TCP Server is used 396 to establish the communication with the EEG Processing Unit. 397 Once the connection with the the Processing Unit (acting as $\frac{1}{429}$ 308 a TCP Client) is initialized, the Server receives the results of 399 the processing over TCP/IP protocol. Consequently, the lap-400 top sends to the Glasses the parameters according to the user's $\frac{1}{432}$ 431 401 selection. 402 433

(iv) Communication between the laptop and the Glasses: The_{a34} 403 aforementioned TCP Server is also used to establish the $com_{_{435}}$ munication between the laptop and the Glasses. Once the $con_{_{436}}$ 405 nection with the the AR Glasses (acting as a TCP Client) is₄₃₇ 406 established, the laptop (Server) can send the parameters to the $_{_{438}}$ 407 user over TCP/IP protocol. An Android application developed₄₃₉ 408 in Android Studio is implemented to receive over TCP/IP pro-440 409 tocol the vital signs, and display them in real-time. 410 441

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411 5. Preliminary metrological characterization of BCI-444 412 SSVEP 445

Before proceeding with the experimental validation and⁴⁴⁷
metrological characterization of the proposed system, an offline⁴⁴⁸
analysis of the BCI dataset was carried out. With respect to⁴⁴⁹
[36], this analysis was focused on taking into account the effect⁴⁵⁰
of frame rate drop in the visualization of the flickering stimuli.⁴⁵¹



Fig. 6: Details of the communication between the devices.

The analysis of the performance of the BCI-SSVEP system allowed to assess the accuracy and the latency of the SSVEP detection algorithm, compared with the demanded requirements for medical application.

The accuracy A is defined as the number of signal fragments correctly classified, divided by the total number of signals, and it is typically expressed as a percentage, as in (6).

On the other hand, the latency is the time needed by the algorithm to classify a signal fragment.

Brain signals of 20 healthy and untrained volunteers were analyzed, after acquiring 24 brain signals per subject.

It should be mentioned that for creating the dataset, the Epson Moverio BT-200 was used as *AR Glasses*, with a nominal refresh rate of 60 Hz. While the AR glasses used for the experiments at the Federico II Hospital were the Epson Moverio BT-350. Nevertheless, thanks to the modularity of the system, this does not represent an issue because the only parameter that changes for the SSVEP stimuli generation and detection is the refresh rate, which has a nominal value of 60 Hz for the Moverio BT-200 and a nominal value of 30 Hz for the Moverio BT-350. However, for practical applications, the Moverio BT-350 represents a better choice because it is more powerful in terms of CPU and RAM: this translates into a better stability of the frame rate.

The luminosity of the environment was (97 ± 2) lx. In this characterization, two stimuli were used, at a nominal frequency of 10.0 Hz and 12.0 Hz. Each subject was asked to focus on one stimulus at a time, for 10 s. After collecting the acquired data, an analysis of the frame rate drop was carried out, obtaining an average frame rate of approximately 59.0 Hz. This leads to a shift of the stimuli frequency from 12.0 Hz to 11.8 Hz. By taking into account this shift, the new performances were evaluated. In Table 1 and Tab. 2 the accuracy and the latency values measured at 3- σ (99.7% confidence level) as a function of T

Table 1: 3- σ Accuracy (%) of SSVEP detection algorithm for different time windows T and threshold values T1.

				T1			
		0.50	0.52	0.54	0.56	0.58	0.60
	0.5	79.6 ± 9.7	81.0 ± 9.3	82.7 ± 8.3	83.3 ± 8.3	83.7 ± 8.0	85.7 ± 7.8
T (s)	0.6	86.0 ± 7.9	86.4 ± 8.2	87.2 ± 8.1	87.7 ± 8.1	88.6 ± 7.6	89.7 ± 6.8
	0.8	91.0 ± 6.2	90.7 ± 6.5	91.2 ± 6.6	93.3 ± 4.7	93.9 ± 4.4	94.6 ± 4.6
	1.0	93.8 ± 6.0	95.0 ± 5.4	94.2 ± 5.9	96.1 ± 3.4	96.0 ± 3.7	96.9 ± 3.8

Table 2: 3- σ Time response (s) of SSVEP detection algorithm for different time windows T and threshold values T1.

				T1			
		0.50	0.52	0.54	0.56	0.58	0.60
	0.5	1.23 ± 0.13	1.30 ± 0.13	1.45 ± 0.16	1.58 ± 0.18	1.82 ± 0.22	2.16 ± 0.25
T (s)	0.6	1.61 ± 0.18	1.81 ± 0.21	1.99 ± 0.23	2.28 ± 0.27	2.55 ± 0.29	2.85 ± 0.32
	0.8	2.54 ± 0.27	2.85 ± 0.30	3.16 ± 0.32	3.50 ± 0.35	4.01 ± 0.37	4.46 ± 0.37
	1.0	3.42 ± 0.31	3.82 ± 0.33	4.17 ± 0.34	4.73 ± 0.37	5.13 ± 0.38	5.72 ± 0.38

Table 3: SSVEP detection algorithm for T = 0.8 s and T1 = 0.56.

Volunteer	Accuracy (%)	Latency (s)
#1	91.7	2.85 ± 1.39
#2	95.5	3.71 ± 1.97
#3	73.7	4.55 ± 2.08
#4	100.0	1.96 ± 0.68
#5	95.5	3.30 ± 1.65
#6	95.5	4.73 ± 1.68
#7	100.0	1.55 ± 0.60
#8	94.4	5.23 ± 1.95
#9	95.8	1.40 ± 0.80
#10	95.8	1.95 ± 0.73
#11	95.8	1.00 ± 0.26
#12	91.7	1.78 ± 0.69
#13	100.0	6.05 ± 1.82
#14	95.2	4.28 ± 2.00
#15	95.8	1.53 ± 0.64
#16	100.0	6.10 ± 2.39
#17	87.0	3.06 ± 1.15
#18	76.5	5.50 ± 2.07
#19	95.5	4.93 ± 1.83
#20	90.9	4.56 ± 1.81
Results	93.3 ± 4.7	3.50 ± 0.35

and T1 are evaluated. The threshold T2 was set to 0.5, which $\frac{1}{473}$ 452 means that the feature F1 must be at least the 50% greater than 453 the feature F2. 454 475

A focus on the SSVEP detection algorithm for T = 0.8 s and 455 T1 = 0.56 is given in Table 3. These two threshold values₄₇₆ 456 were chosen so as to guarantee an accuracy compatible with 457 the healthcare requirements. In particular, the SSVEP recog-458 .478 nition reaches an accuracy of about 93.3 % with a Latency of 459 479 about 3.50 s. 460 480

For comparison, Fig. 7 shows the the difference in terms of₄₈₁ 461 accuracy and latency between the current analysis and the one482 462 reported in [36]. It can be noticed that, between 2 s and 4 s the483 463 accuracy rises by approximately 1.5 %. 464 484



Fig. 7: Accuracy of SSVEP processing: comparison of the results from this preliminary analysis and the results reported in [36].

6. Experimental results 465

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First, the system functionality was validated, with a focus on the frame rate drop related to the generation of the flickering stimuli. Then, the on field results related to the BCI accuracy and latency were obtained. Furthermore, the performances of the BCI System with four flickering stimuli are discussed. Successively, the reliability of the proposed AR-BCI integrated monitoring system was evaluated by measuring the accuracy of the transmission, and the delay time needed by the display to be updated with the vital parameters acquired from the OR equipment.

6.1. Functional Validation

The preliminary validation was carried out to ensure each block of the system architecture worked properly.

In the experiments, the patient's lung was emulated by means of a non-self-inflating bag plugged to the Ventilator. The MED-IBUS communication was established with a Baud Rate set to 38500 bit/s. The patient monitor was used to monitor the vitals of a healthy volunteer. Table 4 summarizes the set of parameters that were collected.

Table 4: Vitals monitored during the experimental tests.

Parameter	Symbol	Unit	Ventilator/Monitor
Compliance	Cdyn	l/bar	Ventilator
Minimum Airway Pressure	Pmin	mbar	Ventilator
Mean Airway Pressure	Pmean	mbar	Ventilator
Peak Airway Pressure	PIP	mbar	Ventilator
Minute Volume	MV	l/min	Ventilator
Spontaneous expired total volume	VTespon	ml	Ventilator
O ₂ Saturation	SpO2	%	Monitor
Compound ECG	ECG	mV	Monitor
Respiratory Rate	RR	1/min	Monitor
Hearth Rate	FC	1/min	Monitor



Fig. 8: Picture of the user wearing the AR-BCI system.

485 6.2. Operation

Fig. 8 shows a picture of the user wearing the AR Glasses and electrodes, with the OR Equipment in background.

Once the laptop and the OR equipment are connected via ca-488 ble, the MATLAB code and the Medicollector software can be 489 launched. The user launches the dedicated Android applica-490 tion and inserts the Server IP address and Port number. Then, 491 four squares flickering at different frequencies appear on the AR⁵¹⁷ 492 glasses display, as shown in Fig. 9. Each square corresponds to518 493 the selection of a waveform coming from the patient monitor;519 in the considered case, the possible selection was among Elec-520 495 trocardiogram (ECG), Oxygen Saturation (O2Sat), Respiration₅₂₁ 496 Rate (RR), and Heart Rate (HR). 522 497

Before acquiring the SSVEP elicited by the flickering stimuli₅₂₃ generated by the Moverio BT-350, the effort needed by the sys-524 499 tem to produce each time a new frame was measured, obtaining525 500 an average frame rate of about 32 fps, higher than the 30 Hz₅₂₆ 501 of BT-350 nominal refresh rate. This leads to the presence of 527 502 undesired multiple frames. Therefore, the code working on the528 503 Android application and related to the rendering of the visual₅₂₉ 504 stimuli was modified taking into account the average fps ob-530 505 tained. Fig. 10 shows the variation of the fps while the Android₅₃₁ 506 application is in execution. 532 507

After executing the code on the Raspberry, the acquisition⁵³³ and processing of the EEG signal starts. The Raspberry sends⁵⁴⁴ the results of the processing to the laptop and, finally, the laptop⁵³⁵ forwards the collected parameters (as selected by the user) to⁵³⁶ the AR glasses. Fig. 11 shows a snapshot of what the user sees⁵³⁷ after selecting the ECG waveform by SSVEP. The user sees⁵³⁸ the main parameters from the ventilator and, at the bottom, the⁵³⁹



Fig. 9: Flickering squares to select waveforms.

Fig. 10: Moverio BT-350 frame rate while running the Android application.

real-time variation of ECG. In this way, the user has complete control of the information.

6.3. Experimental characterization of the BCI performance

After validating the functionalities of the system in relation to (i) the acquisition and visualization of the vital signs and (ii) to the rendering of the flickering stimuli and the EEG processing, the on-field BCI performance was assessed. The flickering frequencies chosen to let the user select the waveforms coming from the patient monitor were 8 Hz, 10 Hz, 12 Hz and 15 Hz. At each run, the user was asked to declare which visual stimulus he was looking at. Table 6 summarizes the user's answers, with the time needed by the algorithm to detect the SSVEP. It was observed that, in three cases, the algorithm could not identify the correct frequency observed.

As reported in Table 6, the frequency value that showed the best performance in terms of both accuracy and latency was 8 Hz; this is due to the fact that the highest frequency values are more sensitive to the frame rate drop. For instance, a frame rate drop from 32.0 Hz to 30.0 Hz leads to a frequency shift from 15.0 Hz to 14.1 Hz, and from 8.0 Hz to 7.5 Hz. Therefore, the SSVEP detection has a higher probability of success at 8 Hz and 10 Hz, rather than at 12 and 15 Hz. Moreover, the luminosity of the environment (147 ± 2) lx and the presence of four squares instead of two, also contributed to the drop of the overall accuracy with respect to the results obtained in Section 5. After the user made

Fig. 11: Snapshot of the user's view after the BCI-made selection.

the selection through BCI, the vital signs are displayed on the 540 AR Smart Glasses. 541

6.4. Metrological characterization of the system transmission 542

The experimental session consisted in 10 runs. As the Medi-543 collector was in free-trial mode, each run had a maximum duration of 180 s. For each run, the measurement of the transmission 545 accuracy was carried out through (6). Then, the mean value and 546 the 3-sigma uncertainty were evaluated taking into account the 547 total number of runs. 548

Finally, the system's delay time, namely the time interval neces-549 sary to update the data coming from the devices, was measured 550 by means of the MATLAB stopwatch timer tic. 551

For each packet within a run, it was possible to evaluate the de-552 lay related to: (i) ventilator update, (ii) monitor update, and (iii) 553 TCP communication. Based on previous experimental cam-554 paigns carried out by the authors [37], the TCP/IP delay was 555 considered negligible; in fact, its value is typically lower than 556 than 2 ms, which fully satisfies the requirements expressed in 557 [41, 42]). For this reason, only the mean value and the stan-558 dard deviation related to the Monitor and Ventilator update de-559 lay were reported at the end of each run. At the end of the 560 session, the assessment of the weighted mean and of the 3- σ 561 propagated uncertainty was carried out (This was done taking 562 into account the different number of packets sent for each run). 563 In particular, the weighted mean of the data-update delay (μ_t) 564 was evaluated through (8). The standard deviation and, conse-565 quently, the 3-sigma uncertainty, were evaluated according to 566

Table 5: Results of BCI processing in terms of accuracy and latency for each 576 run during the experimental session. 577

#Run	Frequency [Hz]	[0-2 s]	[2-4 s]	[4-6 s]
#1	8 Hz	√		
#2	10 Hz		· · · · ·	
#3	12 Hz		·	
#4	15 Hz			~
#5	8 Hz	 Image: A second s		
#6	10 Hz	·		
#7	12 Hz			×
#8	15 Hz		×	
#9	8 Hz		·	
#10	10 Hz			×

Table 6: Summary of BCI performance after the experimental session.

Frequency [Hz]	Accuracy [%]	Mean latency [s]
8 Hz	100.0	2.67
10 Hz	66.7	4.00
12 Hz	50.0	5.00
15 Hz	50.0	5.00
Total	70.0	4.00

the law of propagation of uncertainty, assuming the indepen-567 dence of each run, as shown in (9). 568

Table 7 summarizes the details of the experimental session, con-569 sidering the delay related to the Monitor and Ventilator parame-570 ters update, along with the Accuracy of the transmission. It can 571 be noticed that the accuracy related to the TCP/IP transmission 572 is 100.0%: no errors occurred during the whole test. 573

Table 7: Details for each run of the experimental session.

#Packets	Mean Delay [s]	Std Delay [s]	Accuracy [%]
(i) 149	0.97	0.19	98.0
(ii) 75	1.95	0.37	100.0
(i) 150	1.01	0.22	96.7
(ii) 78	1.98	0.39	100.0
(i) 145	0.95	0.17	97.2
(ii) 75	1.87	0.44	100.0
(i) 156	0.98	0.19	96.1
(ii) 80	1.95	0.39	100.0
(i) 139	0.99	0.21	97.8
(ii) 73	1.92	0.40	100.0
(i) 143	0.97	0.19	98.0
(ii) 73	1.92	0.45	100.0
(i) 132	0.97	0.19	96.2
(ii) 69	1.89	0.47	100.0
(i) 131	0.99	0.21	99.2
(ii) 68	1.93	0.44	100.0
(i) 122	0.96	0.19	97.5
(ii) 62	1.94	0.39	100.0
(i) 126	0.99	0.21	97.6
(ii) 66	1.93	0.43	100.0
TOTAL	Weighted Mean [s]	Propagated Unc [s]	Mean ± Unc [%]
(i) 1393	0.98	0.02	97.4 ± 0.9
(ii) 719	1.92	0.05	100.0 ± 0.0
Logonde			

Legend:

(i) Drager update

(ii) Philips update

7. Conclusion

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An integrated BCI-AR real-time monitoring system for the acquisition and visualization of data from Monitoring equipment was proposed. The system, which relies on the combination of BCI and AR to allow the user to select hands-free which data they want to display in AR, was implemented and validated considering a healthcare application scenario.

In particular, as a case study, the real-time AR-based visual-581

ization of patient's vitals was considered. The data are acquired 582

583 from the OR equipment in real-time, and displayed on the user's

- AR glasses. The user can select hands-free which parameter 584
- should be displayed on the AR glasses, by means of a highly-585
- wearable, noninvasive and trainingless SSVEP-based BCI. 586

The overall system was designed, implemented and validated 587

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through experimental tests using the equipment typically avail-648 588 able in the OR. After a preliminary functional validation, the⁶⁴⁹ 589 system accuracy and delay were assessed for both the BCI and $^{\scriptscriptstyle 650}$ 590 the AR subsystems, thus demonstrating the effectiveness and $\frac{1}{652}$ 591 reliability of the proposed AR-BCI-based monitoring system.653 592 The obtained measured transmission accuracy of the vital signs⁶⁵⁴ 593 is higher than 97%, with a negligible delay introduced by the $^{655}_{656}$ 594 Android application to receive the parameters, preserving the₆₅₇ 595 reliability and real-time requirements that the contexts necessi-658 596 tates and confirming the improvement of AR in the Health 4.0659 597 framework. The on-the-field performance of the single-channel 598 SSVEP-based BCI showed an accuracy of 70% with a latency₆₆₂ 599 of approximately 4.00 s. Further work will be dedicated to im-663 600 prove the SSVEP-detection algorithm: in particular, the intro-664 601 duction of a time-frequency analysis in the processing could 602 mitigate the effects caused by the frame-rate drop, thus improv-667 603 ing the overall results. 668 604 669

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