Educational Material and Manufacturing Minded Class and Course of Biomedical Instrumentation Development for Undergraduate Students

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***Abstract*—Educational materials especially for the undergraduate students who are interested in the field of medical device developments have been developed. As the first attempts, ECG (electrocardiograph) monitor design implemented on a breadboard was planned and evaluated. This design including an instrumentation amplifier with high input impedance (INA118 and 128, Texas Instruments Incorporated, TX) is basic so that beginner can complete implementation and evaluation within a three hours course. Then, undergraduate students in the class can implement the ECG monitor by themselves. ECG waveform, especially QRS-complex, clearly observed. Through some courses of the ECG on a breadboard, a new course of manufacturing education (in Japanese, "Monodukuri-Kyouiku") minded biomedical instrumentation device development is currently being planned and constructed. In the new course, biomedical instrumentation devices such as ECG, EMG (electromyogram), PPG (photoplethysmogram) monitors and so on, will be designed and producted by students themselves. In the course, PCB (printed circuit board) design by CAD software and PCB rapid prototyping by milling systems (FP-21T, Mits Co. Ltd., Tokyo, Japan) are introduced and students will design and build their PCBs and finish them within six hours.**

***Index Terms*—medical device, biomedical engineering education, ECG, computer aided design (CAD), rapid prototyping, fab lab**

I. Introduction

In the background of the current Japanese government's "New Growth Strategy", which promotes the industry of medical devices with a policy of "life innovation" as one of the highest priorities, education of students who are interested in the field of medical device developments should be important topics. However, there are few educational materials which show methods of practical preparation of bio-medical instruments. Student's questions of how to make the device, circuit and/or instrument are only solved by the high-skilled mentor in the educational institute. Then, several institutes appear biased toward analysis of biomedical phenomenon and/or usage of existing devices.

Awareness of the issue in the education of our department is currently focusing on the manufacturing education (in Japanese, this is called "Monodukuri-Kyouiku"). We think it should be ideal that students can accumulate experiences of developing, building and/or manufacturing devices by their own. Therefore, a new class and small sub-course that should include biomedical instrument design and also practical manufacturing of the instruments for undergraduate students is currently worked up. The course or sub-course will for the second or third grade students.

In this paper, attempts of development of the courses and educational materials for biomedical instruments design and manufacturing are described.

II. Methods

A. The First Attempt; Educational ECG on Breadboard

As the first attempt, educational material for implementation of an ECG (Electrocardiogram) amplifier was planned. ECG was selected because it is well-known physiological parameter, measurable non-invasively and having relatively higher electrical potential than other bioelectric parameters such as EMG (electromyogram), EEG (Electroencephalogram) and so on. In this context, higher electrical potential means relatively easier to be measured. Electro dermal activity (EDA) was also a candidate but EDA was not selected because EDA (skin potential activity and skin conductance activity) are highly influenced by mental status of the subject.

As an educational design, the ECG amplifier was designed as simple as possible and implementable on a circuit breadboard. For this simple design, the one-chip instrumentation amplifier built from three op-amps with high input impedance (INA118 or 128, Texas Instruments Incorporated, TX) [1] was employed. With using only the INA118/128 amplifier, it was considered that ECG potential was amplified to be observed. However, the well-known useful technique of the Driven-right-leg (DRL) circuit design [2] to avoid common voltage common mode voltage in differential amplifier was not introduced. The theoretical basis of the DRL circuit behavior is negative feedback for right leg electrode, however, negative feedback of self-regulating

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mechanisms is taught in sixth semester (the last half of the third grade) in our department. Instead of common-mode rejection by the DRL circuit, high-pass filters were introduced in the educational design. Finally obtained design was considered as a material with which a beginner can complete implementation and evaluation within a three hours class. The final design is shown in Fig. 1 and its specification is shown Table I.

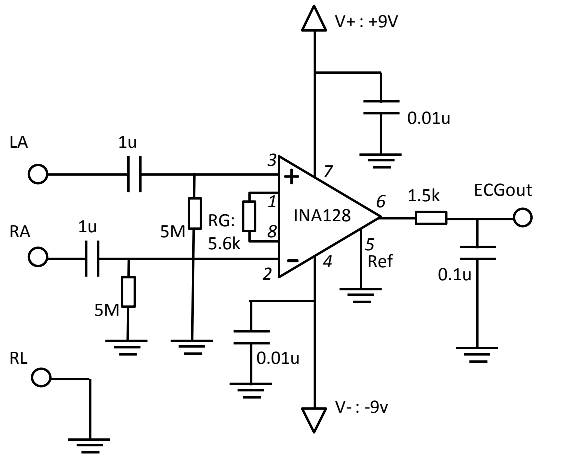


Figure 1. ECG amplifier design for educational material. The resistance RG (5.6kΩ) provides gain 20 dB. High-pass filters are 1uF-5MΩCR filter related to left and right arm electrodes (RA and LA). Low-pass filter are 0.1uF-1.5kΩCR filter related to the amplified ECG signal (ECG out). RL means right leg electrode (reference electrode).

TABLE I. BASIC CHARACTERISTICS OF THE EDUCATIONAL ECG

Information	Details
Total gain	x10 (20dB)
Cut-off frequency of high-pass filter	0.039Hz(-3dB)
Cut-off frequency of low-pass filter	1.06kHz(-3dB)
Input impedance of working electrodes	5×10^{6} // $10^{10}\Omega$ ("//" means parallel connection, $5\times10^{6}\Omega$ is by high-pass filter, $10^{10}\Omega$ is by instrumentation amplifier INA118)
Power supply	Two 9V batteries

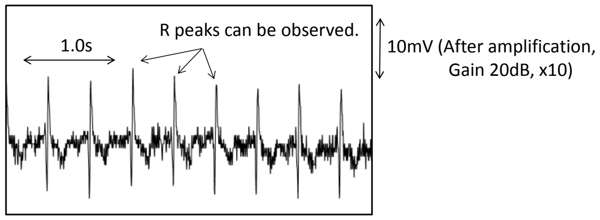
B. The Second Attempt; Educational ECG Prototyping with Rapid Prototyping Methods

For student who complete the breadboard ECG implement course as described above, an advanced sub-course is planned and under being evaluated. The advanced sub-course includes a physiological monitor design and its printed circuit board (PCD) design, fabrication and mounting. For PCB design, some CAD software are introduced. As CAD software, CADLUS one (Nisoul Co. Ltd., Sayama, Japan), Ki-Cad (KiCad Developers team) and Fritzing (Friends-of-Fritzing foundation and IXDS) is being evaluated. In order to fabricate PCB by students themselves, rapid prototyping systems; FP-21T milling machine (Mits Co. Ltd., Tokyo, Japan) and customized iModela iM-01, a numeric controlled table-top milling machine (Roland DG Corp., Tokyo, Japan) are introduced. Furthermore, a through-hole plating line is also introduced to making through-holes in PCBs.

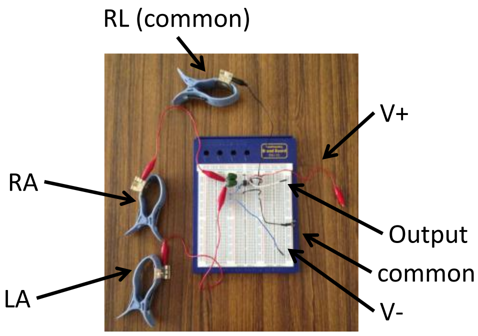
In the sub-course, student will try to design and fabricate physiological monitor such as ECG, EMG (electromyogram), PPG (photoplethysmogram) monitors and so on by themselves. Students can design and build their own PCBs and finish them in six or nine hours. Currently, voluntary students are trying to make their own circuit as a pre-evaluation course to prepare an official start of the new sub-course.

III. RESULTS

In the first attempt, undergraduate students of third grade (in their fifth semester) can implement the ECG monitor by themselves as Fig. 2 (b). ECG waveform, especially QRS-complex, clearly observed (also shown in Fig. 2 (a)). The waveform is not so clear because this design does not only include the DRL circuit for avoiding electric hum, but also any active high-order filter. High input impedance of the amplifier should be easily affected by noises. Additionally, wires and contact plates in breadboard circuit are much more susceptible to electro-magnetic noise pickup as it hangs in the air. Noise by electrostatic phenomenon should also affect. But, as the first experience for student, it should become impressive. The DRL feedback and active filter design should be the next issues to be learned.



(a) Example of obtained waveform by educational ECG monitor.



(b) ECG implemented on a breadboard.

Figure 2. ECG amplifier implemented by an undergraduate student (panel b) and example of obtained waveform (panel a).

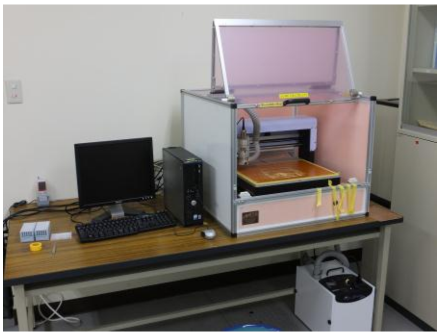
Through some class of the educational ECG on a breadboard, currently, we are planning the second attempt described above. The new sub-course will be for manufacturing education (in Japanese, "Monodukuri-Kyouiku") minded biomedical instrumentation device development such as ECG, EMG (electromyogram), PPG (photoplethysmogram) monitors and so on. For the attempt, a rapid prototyping factory has been constructed in our department. Almost of the equipment installed in the factory have been selected as apparatus that can be easily operated or easily obtained operation skills. The installed apparatus are listed on the Table II and some of them are presented as Fig. 3.

Voluntary students are currently evaluating the manufacturing equipment in making their own devices especially for biomedical instruments. Fig. 4 shows an example of an ECG amplifier designed and fabricated by a third grade student. In contrast to previously described ECG on breadboard, it includes DRL circuitry and higher-order active filters. This ECG amplifier is currently being evaluated, and the evaluation process is also being designed by the student himself.

IV. Discussion

The manufacturing education (in Japanese, “Monodukuri-Kyouiku” or “Monozukuri-Kyouiku”, “zu” and “du” have same pronunciation in Japanese) is one of education styles that have recently considered crucial to Japanese “Monodukuri” style industry or the industry of manufacturing and systems environment integration [3]. The definition of the education style is underspecifying, but, it should be generally for bringing up a student as a developer of devices, not user of the forefront device. In another term, these educations are not for fabless style companies, but for companies with designing and fabricating their own products.

In the field of biomedical engineering, there have been many discussions about learning and education. One worth noting current of it should be odyssey based on the country's characteristic. As examples, Douglas tried to describe an educational style especially for developing countries [4]. Magjarevic *et al.* summarized and reviewed biomedical engineering programs related to education in EU [5]. Zheng and Chen reported biomedical engineering education in China [6]. Meanwhile, we have especially focused education of biomedical engineering with manufacturing process. While our attempts are partly based on Japanese culture that respects fabrication and supports fabricator [7], consecutive education process from circuit design to fabrication should be valuable.



(a) Milling machine for PCB (FP-21T, MITS)

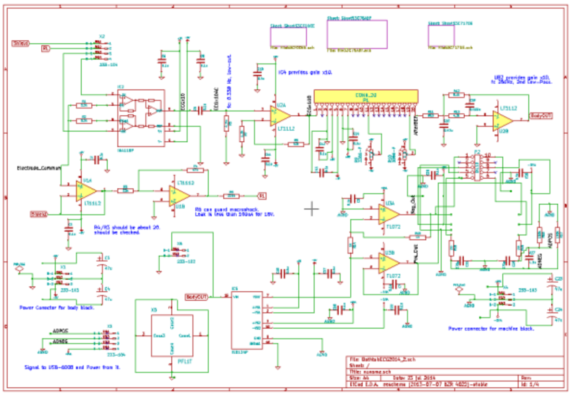
(b) Through-hole plating line (center) and Spray etching machine (left) (Compacta 30 and Splash, Bungard Elektronik)

(c) Dry Film Laminator (RLM 419p, Bungard Elektronik)

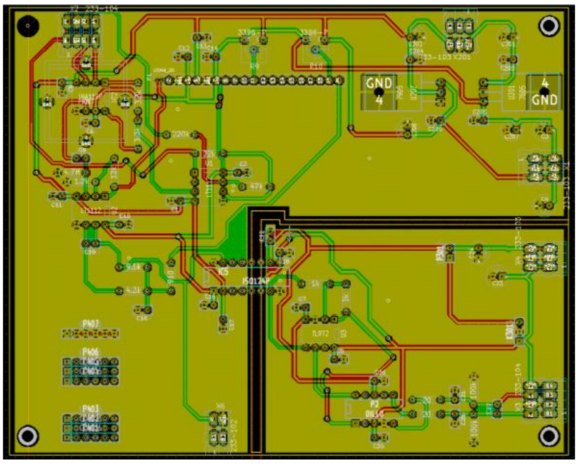
Figure 3. Example of equipment installed in our rapid prototyping factory for education.

TABLE II. Installed Apparatus in the Educational Manufacturing Factory

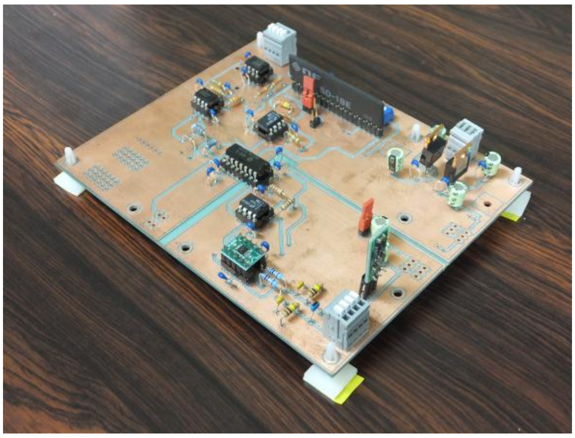
Apparatus and software	Type/Name	Manufacturer / Developer
Milling machine	FP-21T	MITS, Japan
	iM-0	Roland DG Corp, Japan
Through-hole plating line	Compacta 30	Bungard Elektronik, Germany
Spray etching machine	Splash	Bungard Elektronik, Germany
Dry Film Laminator	RLM 419p	Bungard Elektronik, Germany
Screen printing machine	SR-251	Sunhayato, Japam
PCB cad software	CADLUS one	Nisoul Co. Ltd., Japan
	KiCad	KiCad Developers team
	Fritzing	Friends-of-Fritzing foundation and IXDS



(a) Part of schematic of ECG amplifier



(b) PCB design of ECG amplifier



(c) ECG amplifier by a voluntary student. PCB is fabricated in our factory and all electronic parts are already mounted.

Figure 4. Example of ECG amplifier designed and fabricated by an undergraduate student.

Difficulty of this style of manufacturing minded education should be catching up a forefront technic and/or field. For example, it should be difficult to fabricate a magnetic resonance imaging device in ordinary university. Especially in the frontier fields of mega-science this concept should not work. However, many hot-topic fields should be with the manufacturing education. One of these examples should be optical coherence tomography (OCT). OCT setup can be realized in optical bench experiment. Another example would be the PCR thermal cycler. Recently, Jankowski and Perfetto proposed an open-source hardware design of PCR machine that anyone can build [8]. In another field, CPU design education by using FPGA may have same purpose, because students can have own CPU design. Speaking of CPU design using FPGA, initial cost is inexpensive than our PCB design education. Currently, FPGA prototyping board can be bought for less than 300 USD and the FPGA developing environments are offered free from FPGA companies.

Another problem should be a possible conflict during education, practical engineering and scientific values. Current strategy is standing on the importance of national strategies and/or characteristics of Japan nation; request of enhancing biomedical engineering industry and Japanese style the industry of manufacturing and systems environment integration. Educational problems are under consideration. Example of another group, Becker *et al.* reported their attempts including physiological measurement; a photoplethysmograph circuit design. Their attempt should be similar with our educational material and course design. However, their description is mainly focused on the educational methodology of active learning and inquiry-based methods [9]. Specific problem in education of biomedical engineering appears free of discussion in their description. To be truthful, this is same as this paper. Though the authors are specialists of engineering and one of them should be the biomedical engineering specialist, it has been difficult to catch up the forefront current of learning technology field. While in the information science and/or technology fields, learning technology appears well integrated to the education, in the biomedical engineering field, it is still difficult to design and/or evaluate educational schemes in the context of learning technology.

In previous description, Japanese style manufacturing based industry and education are focused, however, our attempts are also profoundly affected by the "fab lab," that is a small-scale workshop/factory offering digital aided fabrication [10-13] risen up from MIT. The key technologies of the "fab lab" concept should be same as ours, which should be relatively small scale numerical controlled fabrication tools and computer aided design tools (recently, personal computer based design software). The fact that a class named "How To Make (Almost) Anything" based on the "fab lab" has been offered at MIT could be the evidence to solve the problem described above; conflict during education, practical engineering and scientific values. The difference between the "fab lab" and our attempt would be those purposes and goals. Sometimes, the "fab lab" is focusing on the personal fabrication and/or small lot production of many products (in another term, high-mix low-volume production, limited production of diversified products). Our attempts are mainly focusing on engineer education.

V. Conclusion

Development of educational materials for biomedical instruments design has been attempted and described. In the class, the simple design of an ECG monitor was given for undergraduate students and they were able to implement the ECG monitor in a solder-less breadboard by themselves. Currently, the new course of biomedical instruments design including PCB fabrication is under constructed.

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