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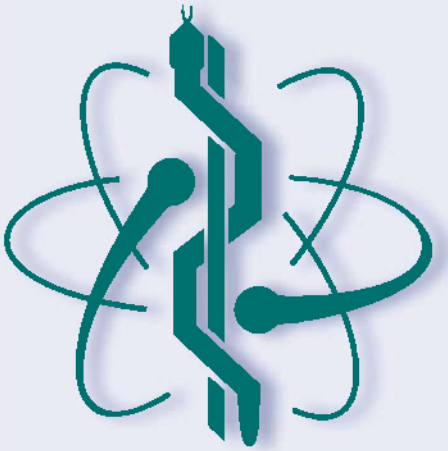

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# Treatment of Abdominal Hypertension: Development of an Original Non-invasive Device ABDOPRE

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**Abstract. ABDOPRE** is a device that reduces the abdominal pressure of intensive care patients with intraabdominal hypertension. The controlled reduction following a time protocol is consequence of the application of an external negative pressure inside a vacuum bell affixed to the patient's abdomen. Originally developed in 2007, **ABDOPRE** was tested in four intensive care patients with intrabdominal pressures (12 to 15 mmHg). In three of these patients a reduction of 5 mmHg, 3 mmHg and 2 mmHg was accomplished. Afterwards, a new, cheaper, smaller and lighter version of **ABDOPRE** was developed using an ARDUINO UNO board for the control system and an ARUINO UNO SHIELD for the electrical interface. This version has an optimized Software and includes two bell sizes of 14 and 24 L respectively.

**Keywords:** Abdominal hypertension · Intra-abdominal pressure · Clinical instrument

## 1 Introduction

Intraabdominal hypertension (IAH) and abdominal compartment syndrome (ACS) are associated with pathologies that frequently affect intensive care patients. It is paramount to monitor and control these conditions as they have numerous pathophysiological implications. IAH is defined as a sustained or repeated pathological increase in intraabdominal pressure (IAP) above 12 mmHg. ACS is defined by a sustained increase in IAP above 20 mmHg that is associated with organ dysfunction or failure [1, 2]. In both cases, IAP elevation may have consequences in the nervous, cardiovascular, respiratory, hepatic, gastrointestinal, renal or endocrine system as well as potentially damaging the abdominal wall [3, 4]. Both IAH and ASC may cause a multi-organic failure and therefore increase the patient's mortality risk. Nowadays, the usual practice for reducing IAP when other non-surgical methods fail, is decompressive laparotomy [2]. Nevertheless, this is an invasive procedure and therefore there is large consensus [3] in searching for alternative less traumatic methods for reducing IAP that avert the potential complications inherent to any surgery. **ABDOPRE** was developed in 2007 [5] in response to this need, enabling a


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controlled and non-invasive reduction of IAP through the application of a negative external pressure (NEXAP) above the patient's abdomen. Research has been done on the use of NEXAP to treat HIA [6, 7]. However, a specific device that allows a controlled reduction of IAP is yet to be developed. This paper analyses the different stages in the development of such a device, **ABDOPRE,** since its conception to the latest version on trial, describing its subsequent updates.

## 2 Operating Principle

**ABDOPRE** is based on the idea that IAP can be reduced through the controlled application of an external negative pressure. In previews works [8] we modelled the abdomen as a cuboid body filled with gases and liquids whose only compressible wall is its anterior wall. Assuming the abdomen is a compressible body which obeys the isothermal compression equation, we showed that changes in the pressure inside the bell are inversely proportional to abdominal volumen changes. Then, assuming abdominal gases obey the Ideal Gas Law, we proved that a reduction in the pressure inside the bell leads to a reduction in IAP which is the main idea behind **ABDOPRE** [8].

The system has four main functional blocks: a vacuum chamber or bell affixed to the patient's abdomen, a vacuum pump, a signal acquisition and control module and a graphical user interface. **ABDOPRE** has two pressure transducers, one that senses IAP through an intravesical catheter and another one that measures the pressure in the bell.

The clinical staff chooses the treatment protocol that consists in applying repeated positive and negative pressure slopes with pauses without applied pressure and periods of maximum applied pressure [9]. The simplest protocol is specifying the initial patient's IAP, the target IAP, the tolerance margin for the IAP and the duration of the treatment. Let $IAP_o$ be the patient´s initial IAP, $IAP_f$ the target IAP and $t_{treatment}$ the duration of the treatment, the control system creates the following linear reduction pattern for the IAP:

$$\mathrm{r(t)} = \frac{-\left(IAP_o - IAP_f\right)}{t_{treatment}} \times t + IAP_o \tag{1}$$

### 2.1 Protocol for Reducing and Maintaining IAP

Let $\Delta IAP_{max}$ be the maximum tolerance for the IAP, the control system turns the vacuum pump On and Off according to the following criteria:

$$If\ IAP(t) > r(t) + \Delta IAP_{max} \rightarrow PumpON$$

$$If\ IAP(t) \leq r(t) - \Delta IAP_{max} \rightarrow PumpOFF$$

The pump creates partial vacuum inside the chamber that in turn causes abdominal distension and therefore a reduction in the IAP. Once the target IAP is achieved, the

linear reduction pattern is replaced by a plateau and the control system keeps commanding the pump in order to maintain the IAP within the target range [9].

## 3 ABDOPRE 2007

The first prototype, **ABDOPRE** 2007 [5], included a PIC 16F687 microcontroller [10] as the control system which received the analog pressure values form the two transducers 143PC03D [11] and communicated bidirectionally with the PC through the UART port. The PIC controlled the functioning of the vacuum pump CZ-79600-02 [12] and sounded an alarm in case the chamber was misplaced which was deduced from a time analysis of the variables. The power supply for the transducers used to measure IAP and pressure in the chamber was delivered from an external medical-grade power source whereas all the other parts of the system were powered by a mains connected power source. The 2007 prototype included only one chamber size. The chamber was made with acrylic and its edges were covered with polyphon surrounded by vulcanized silicon in order to ensure a soft and hypoallergenic contact with the patient's skin. The Software displayed the IAP, the pressure in the chamber and the target IAP according to the chosen protocol. It was developed in Scilab with a total of 1075 lines of code. The **ABDOPRE** cabinet had a volume of 2520 $cm^3$, weighted 1.6 kg, and was linked to the chamber and the medical-grade power source. **ABDOPRE** 2007 costed 714USD without considering the development cost of 1400 person-hours.

## 4 Clinical Trials of ABDOPRE 2007

**ABDOPRE** was tested in four intensive care patients with IAP between 12 and 15 mmHg. An example of the application of **ABDOPRE** to a patient is presented in Fig. 1.

Three of the patients treated with **ABDOPRE** showed a reduction of 5 mmHg, 3 mmHg and 2 mmHg in IAP, while a fourth patient showed a 38% increment in IAP with respect to the initial IAP. What happened was that, as the patient was obese, the chamber was intromitted in the abdominal wall reducing the abdominal volume and consequently causing the IAP to increase. The three patients in which **ABDOPRE** was successfully applied showed an average 25% reduction in the IAP with respect to its original value for a period of one hour. In all cases the treatment lasted 10 min and a pressure of -35 mmHg was needed in the chamber in order to achieve the target PIA. The remaining case encouraged the redesign of the chamber in order to adapt it to different abdominal sizes and therefore avoid the 'Ventosa effect' with paradoxical increase [13].

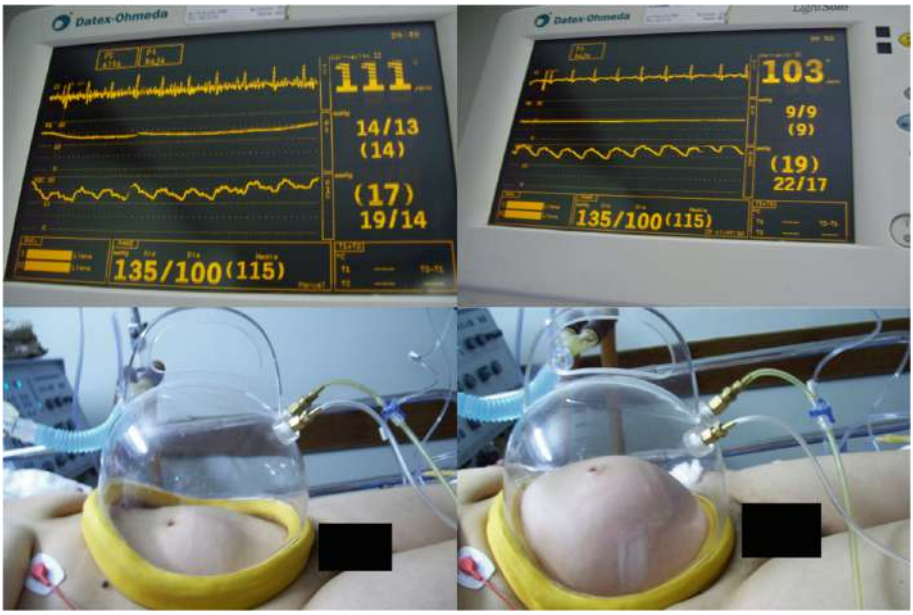


**Fig. 1.** **ABDOPRE** applied to a patient. The patient's abdomen distends when an external negative pressure is applied. In the picture in the left the patients has an IAP of 14 mmHg while in the picture in the right the patient has an IAP of 9 mmHg [13].

## 5 Redesign of the Bell

To ensure the proper function of **ABDOPRE** it is of extreme relevance to guarantee that the chamber is secured upon firm footholds: the iliac crests, the sternum, the pelvic bone and the costal arcs. Only one chamber size may be too small for some patients and the chamber may get intromitted in the abdominal wall when the negative pressure is applied, as was the case in the 2011 clinical trial [13]. In order to lift this restriction and enable **ABDOPRE** to be applied to as many patients as possible, the bell was redesigned in collaboration with Industrial Design students and staff of the Escuela Universitaria Centro de Diseño (EUCD) of the Faculty of Architecture. A sample of 19 intensive care patients were measured to determine how many chamber sizes were needed. This data was mapped in a histogram that revealed that two sizes were enough to fit all the measured patients. Then, 19 more patients were measured to make sure their abdomen fitted one of the two sizes. Based on this information, two new transparent methacrylate chambers were designed weighting 250 or 370 g and of capacities of 14 or 20L respectively [14].

## 6 ABDOPRE 2016

The circuitry and code of **ABDOPRE** were redesigned in 2016 in order to reduce the size, weight and cost of the device and to improve its performance. The original transducers were replaced with Argon DTXPlus TNF-R transducers [15] which are frequently used in intensive care. Additionally, the control system was implemented in an ARDUINO UNO board and the electrical interface in a SHIELD ARDUINO UNO [16] due to its low cost, versatility and ease of duplication. The ARDUINO UNO board communicates with the PC, samples the IAP and the pressure in the bell and commands the pump. Likewise, the SHIELD ARDUINO UNO supplies power to the pump and transducers and amplifies the transducer signals. Finally, for practical reasons and to ensure the patient's electrical safety, the power source was replaced by a battery. All the components fitted in a 3D-printed PVC box of 378 $cm^3$ and 200 grs. **ABDOPRE** 2016 cost less than USD 450. A comparison between the original and the latest cabinet, made in 2017, is presented in Fig. 2.

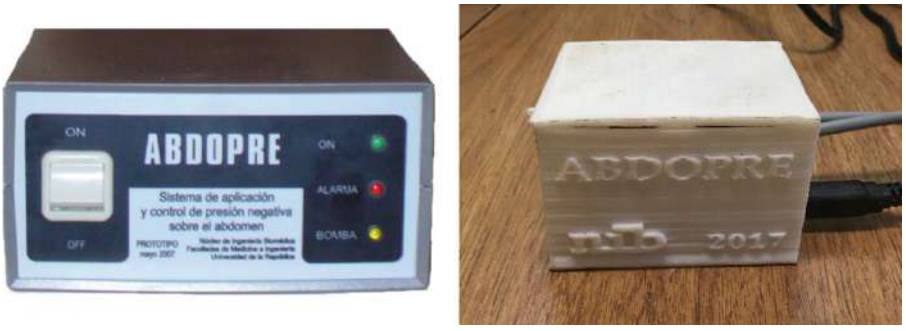


**Fig. 2.** **ABDOPRE** cabinet in 2007 [9] and 2017. Volume was reduced from 2520 $cm^3$ to 378 $cm^3$.

## 7 Trial Phantoms

Several phantoms were designed to test **ABDOPRE**. In the early stages of the development of **ABDOPRE**, water and beer bottles where used to calibrate the pressure measurements taken with the transducers. The bottles were insufflated with different amounts of air using a bicycle pump in order to simulate the positive pressure inputted to the transducers. Then, the pressure in the bottles was simultaneously measured with an analog water column pressure gauge, a digital EXTECH HD750 [17] pressure gauge and the evaluated transducer. The results obtained validate the reliability of the pressure measurements taken with the transducers.

Furthermore, a phantom was specially designed to assess the global performance of **ABDOPRE**. This phantom is a semi-sphere made of acrylic that has rigid walls and an upper part made from a rubber membrane that simulates the abdominal wall. The phantom has a tight fit with the vacuum chamber. In order to emulate the different

conditions of distensibility and content of the abdominal wall, the phantom has a plug that can be extracted to fill it with different amounts of water and a valve to insufflate it with different amounts of air. Moreover, it has an opening through which a catheter can be introduced to measure the internal pressure. This phantom enables the analysis and adjustment of **ABDOPRE** without having to involve a patient [9]. Figure 3 shows **ABDOPRE** applied to this trial phantom.

**Fig. 3. ABDOPRE** 2007 bell applied to the phantom and rear part of the cabinet [9].

## 8 Results and Discussion

We developed a first version of **ABDOPRE** in 2007 which proved to be effective in reducing the IAP of three intensive care patients. Subsequently, based on a statistical analysis we designed two bell sizes aimed to fit most patients. We also developed several trial phantoms in order to asses and adjust **ABDOPRE** without having to involve a patient. In 2016 we developed a second version of **ABDOPRE** which is more than six times smaller, eight times lighter and costs half the price of the original version.

A recent study [18] with 491 intensive care unit (ICU) patients from 15 different clinical settings showed that IAH occurred in almost half of all subjects. In addition, the presence and severity of IAH during the first 2 weeks of the ICU stay significantly increased 28- and 90-day mortality. Ten years have passed since the conception of

**ABDOPRE** and IAH and ACS remain to be concerning and prevalent medical conditions usually treated invasively. **ABDOPRE** offers a non-invasive and practical alternative for progressively reducing IAP. The first clinical results of **ABDOPRE** original version suggest its ability to reduce IAP. Further research will include clinical trials of the latest version to confirm our findings and assess its clinical effectiveness in preventing and treating IAH.

## 9 Conclusions

This paper aimed to gather every contribution made throughout the years in pursuit of the original development and the improvement of **ABDOPRE.** Despite a decade has passed, **ABDOPRE** is still a disruptive project since no descriptions of similar devices were found neither in the literature nor on the market. Moreover, it represents a clear example of what may arise from the synergy between medicine and engineering since the clinical need and idea were introduced by an intensive care medical team in cooperation with biomedical engineering staff. Development was done as master´s theses by Electrical Engineering students assisted by Industrial Design students. This close interdisciplinary collaboration resulted in an efficient, safe, ergonomic and therefore useful system. With the evidence of successful clinical trials of the latest version, **ABDOPRE** has the potential of becoming the usual therapy for controlled IAP reduction during the treatment of IAH.

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**Conflict of Interest.** The authors declare that they have no conflict of interest with respect to the biomedical instrumentation research described in this paper.

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