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A Modern Approach To Traditional Chinese Medicine

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Abstract: Traditional Chinese Medicine (TCM) is consisting of many practices that are common in East Asia. These practices have been around for more than 2000 years. Many of these methods are becoming increasingly popular in the Western world, where they are classified as alternative or complementary medicine. Most of these techniques are untested and some are even considered dangerous in the modern day world, however, they are sometimes able to help, where modern medicine can not. Therefore, it would be wrong to totally reject them. The SINOPOLL project is a joint R&D effort between Thor Medical Systems LLC and their Chinese partner Shenzhen Anke. Its goal is to combine the vast traditional knowledge in TCM with modern day medical system technology. This paper gives an overview of this research, as well, as proposes several possible solutions for common problems in this field.

Keywords: Rehabilitation engineering and healthcare delivery, Decision support systems for the control of physiological and clinical variables, Pharmacokinetics and drug delivery

1. INTRODUCTION

Herbal medicine is among the most widely used traditional practices in china. In contrast to modern medicine, Chinese people tend to turn to it in order to cure many less severe illnesses or many chronic conditions, which can not be helped by western medicine. In other parts of the world TCM is considered as alternative or complementary medicine. TCM consists mainly of herbalism, acupuncture and therapeutic massage. This work focuses mostly on the Chinese herbal medicine, and its new applications.

TCM actively uses more than 1000 different materials, primarily plants, but there are some minerals and animal products as well. With these ingredients, they can successfully cure many different diseases. These materials are almost exclusively mixed together, following recipes, to prepare potions. Some potions are used for inhalation. Most of these medications are available in over-the-counter (OTC) form; therefore it is hard to create statistics about their usage. A study, made in 2010 in Hong Kong by CH Chung et al. (2010.) revealed that a total of 50.8% of the questioned population used some kind of OTC western medicine, and a total of 26.2% of the respondents reported consuming Chinese OTC medication in the previous year. They also noted that “patients with chronic diseases on western medications are also likely to consume Chinese herbal medicines”. Very few comparative studies exist to confirm or deny the TCM-s effectiveness in contrast to modern medical applications. This is mostly because the traditional Chinese healers reject direct comparison with the western doctors. Therefore it is hard to objectively verify their methods, but it is not our goal either. It is also important to state, that TCM methods are not considered as replacements for effective conventional medicine, but rather as complementary methods. As such, they can provide hope in situations, where modern medicine is ineffective yet.

One of the few existing studies by Chang et al. (2011.) proves that the inhalation of complex Chinese medicine can help asthma treatment. They show that the TCM can be used effectively in the early stages of asthmatic diseases and as a preventive method as well. They however conducted their experiments only on guinea pigs. More research is obviously needed in this field, but this result is very important. Nowadays, many Chinese people live in large cities, where the air pollution is increasing rapidly. Therefore the number of respiratory illnesses is also increasing, and it is now a significant problem.

Thor Medical Systems proprietary sensor technology can mean a significant advantage in diagnosing many kinds of respiratory illnesses.

The other field, in which modern technology can be used in TCM, is providing a new way for administering these complex medicines trough automatic inhalators. Therefore the research consists of two main parts, new diagnostics methods and new administering methods for TCM.
Another significant part of the project is cost reduction, because modern, complex medical devices are increasingly expensive, and as such, can not be afforded for home use. It is a serious drawback in our case. Therefore while designing our devices cost effectiveness and low cost design will be a top priority. Also ergonomics, ease of use and functional safety are important aspects.

2. DIAGNOSTICS

2.1 Traditional diagnostic methods

The TCM view the human body and the causes of illnesses differently from Western medicine. More importantly, it does not include objective, quantitative measurement methods like the ones used by modern medicine. The most important diagnostic methods in TCM are the visual examination of the tongue, and audio examination of the pulse and breathing. Traditional diagnostic methods are widely documented in the work of Marcus and Kuchera (2005.). These are however subjective methods that rely solely on the practitioners’ experience, since no objective data can be measured. It is especially hard to recognise the lung related and respiratory illnesses that are mostly induced by modern day problems like city life and industrialization. These illnesses are however becoming increasingly common in China and in other parts of the world as well. Because the practices of TCM date back several hundreds or even thousands of years, TCM is not prepared to effectively treat these kinds of modern life related illnesses. An instructive example was the 2002 epidemic outbreak of the severe acute respiratory syndrome (SARS) in China that has later spread to other parts of the world due to global air travel. After that, many researchers recognised that the integration of TCM with modern medicine (MM) yields promising results in the treatment of SARS. Chen, Gou and al. (2007.) summarized the available works in this field and came to the conclusion that the experience with the integration of TCM with MM in the treatment of SARS was encouraging, and thus more such work is needed.

The increasing numbers of asthmatic diseases show that new, objective respiratory diagnostic methods for TCM are needed. Integrating modern spirometry with traditional methods could be the solution.

2.2 Modern sensor systems

Traditionally, a spirometer is an instrument for measuring the air volume, which is entering and leaving the lung over time. The overall volume of the inhaled or exhaled air can be used to determine lung capacity, while the time function of the air flow (spirogram) contains even more information. It is an important diagnostic method in modern medicine, because it provides reliable, repeatable measurement data that can be compared with standardized norms. Deviations can be measured and assessed to provide means for diagnosing different respiratory illnesses.

Thor Medical Systems offers a specialized, innovative ultrasonic flow measurement technology in their highly integrated spirometers and cardio-pulmonary diagnostic stations. The main component of these systems is the proprietary WaveFront sensor. This sensor can be used in any medical respiratory device, including spirometers, medical and industrial ventilation systems. The sensor is small and compact; therefore it can be effectively used in lightweight, portable systems. The main operating principle behind this device is multipath ultrasonic flow and volume measurement. Ultrasonic flow measurement is adequate for medial spirometry because it does not place any obstacle in the airflow’s way, therefore enables high accuracy measurements, and is easily calibrated. More importantly, the sensors’ accuracy does not deteriorate over time.

The ultrasonic measurement is more favourable, compared to standard, volume measurement based methods because it gives results inherently in the standardized BTPS (body temperature and pressure, saturated) units (Miller, Harkinsson et Al., 2005.) and does not require correction. Moreover, these sensors can be more easily maintained, cleaned and disinfected. Therefore enabling a completely reusable construction, and reducing costs. Due to the small size of WaveFront sensors, they can be integrated into medical ventilation systems, where they can be used for continuous feedback and monitoring. It is also possible to build cost effective measurement and data acquisition devices to be used by patients at home. These home devices can help detecting respiratory problems even while the patents are sleeping, or can be used as continuous monitoring devices in the rehabilitation stages.

Devices useable by patients (like the “Otthon” mobile handheld spirometer) can be equipped with simple voice readout for communicating automated measurement results. The device can also explain to the patient its own usage with a tutorial comprising simplified video and audible text. In case of a poor maneuver such as coughing, slow starting, poor effort, short expiration, or failed reproducibility, the device explains the reason of the poor maneuver to the patient with human voice and also provides a direct tutorial which focuses on the reason of the poor maneuver. The SpiroThor devices are also equipped with a decision support system to help general practitioners, who do not have to have in depth training in evaluating the measured spiograms.

3. TREATMENT METHODS

As previously mentioned, TCM mainly uses herbal medicine to cure respiratory illnesses like asthma and COPD (chronic obstructive pulmonary disease). These herbal ingredients are mixed together and boiled in water to form different potions. The potions (that can be considered as water based solutions) can be applied orally, or inhaled in gas or mist form. Chang et al. used nebulisation to administer the potion in their animal experiments.

Nebulisation is a widely used practice for administering medication directly into the lungs, in the form of a mist. It works by breaking up the medical solution to small droplets which when inhaled, can reach the lower airways. Originally,
nebulisers commonly drive pressurized air or oxygen through the medical solution to form the droplets. Modern nebulisers (like ThorMed’s InhalaThor) utilise ultrasonic power to form a mist, therefore they can be more compact while also creating smaller sized droplets. Droplet size directly relates to the efficiency of the nebulisers, as smaller droplets have better chance to reach the lower and narrower branches of the airways.

The ultrasonic nebuliser is a favourable delivery method for inhalation of complex TCM, because it can be integrated into a medical ventilation system. In such cases, the traditional medication can be used to improve rehabilitation of people who are unable to breathe sufficiently. The disadvantage is that controlling the exact dosage of the medication is more complicated than with other methods for example metered dose inhalers (MDI).

A nebuliser can also be integrated with the spirometer sensor for the proposed home patient monitoring system that – as explained before – can be used to continuously or remotely monitor patients. This integrated system can therefore be used, not only to monitor the patients, but to slowly and automatically administer their required medication. The main problem with the integration is how the spirometers’ sensor will respond to the various medicines mixed in the air. Our proprietary signal processing algorithm used in the WaveFront sensors can be modified to include necessary compensation for accurate measurement under the different conditions. The sensors mechanical construction allows its application with nebulised medications. The inner surface of the flow tube is continuous and there are no moving parts inside the device. Therefore it does not obstruct airflow, so sediments can not occur. The construction of the sensor also enables easy cleaning between different medications.

A significant advantage of this concept is that the dosages can be precisely controlled. Care must be taken for accurate dosage control and possibly new sensors will be needed to achieve this.

4. LOW COST DESIGN

The target market for these technologies is mainly home care. The aforementioned diagnostic and treatment systems are designed to be usable for everyone, even at home by patients. Because of this, it is unavoidable to reduce the production costs as much as possible. This can be achieved in many different ways. Most of these are not suitable for our case.

4.1 Cost reduction methods for medical devices

Mainly, the cost of medical systems is consisting of the following: hardware component costs, assembling costs, software or hardware development costs, and maintenance costs. For devices produced in large numbers, component costs and assembling costs dominate over the development costs, because they are proportional to the production number, where development costs are fixed. Therefore, it is advisable to implement most of the functionality in software, because it only increases the development costs, where additional hardware elements increase both the component and the assembly costs. An additional option for cost reduction is to use mass produced, commercially available components, because their price is much lower. Maintenance costs can be reduced by applying specific active software and hardware solutions for example self calibration or cleaning, but also by passive means, such as a simply cleanable or fully reusable construction.

Hardware component cost reduction can be achieved the easiest way, by redesigning the user interfaces. Due to the popularity of touch screen devices, the price of resistive touch screen technology has dropped significantly. A touch panel with a moderately sized display is now much cheaper than many different switches, pushbuttons, or potentiometers. Therefore it is advisable to outfit the proposed home diagnostic and treatment devices with such touch screens. It is not only favourable as a cost reduction method, but it is an important ergonomic improvement as well. Also the devices’ software can become more complex, and has the option for later upgrades. On the other hand, complicated touch screen user interfaces can increase the software development cost significantly, so there is a trade-off. Display panels with touch screens are also much easier to clean than mechanical controls. They require absolutely no moving parts, and can be completely sealed, therefore water- and dustproof. The reduction of the numbers of switches and potentiometers also mean the reduction of moving and thus deteriorating parts, and it also reduces costs. Table 1 shows the possibility of cost reduction with touch screens, by showing two user interface alternatives for performing the same function.

| Component name and purpose | Traditional user interface | Touch Screen interface |
|----------------------------|----------------------------|-----------------------|
| 3.5” Graphic LCD           | $13                        | Approx. 3$            |
| 4 way navigation button for on screen menu navigation | $3 | Approx. 1$ |
| 2 push buttons for applying or cancelling menu functions, and 4 for use as soft keys | $1 | Overall cost: Approx. 23$ |
| Rotational encoder for setting specific parameter values | $2 |  |
| Button caps and additional plastic front panel parts and markings | Approx. 3$ |  |
| Additional board space     | Approx. 1$                 |  |

Another method for hardware cost reduction is by carefully choosing the applied parts. For example using multi-layer ceramic capacitors instead of solid tantalum/aluminium electrolytic where capacitance requirements allow yields a lower overall cost, higher performance circuit operation with lower board space requirements. Certain circuit elements do not need to be accurate values, for example pull up/down...
resistors, decoupling capacitors, or logic level switch transistors. By using the same type of components everywhere, where requirements allow, lower price can be achieved due to price break at higher volume orders. A suggestion is to use only 47k 1% as pull up/down resistors (where switching speed allows), BSS84/BSS123 field effect transistors (FET) for generic logic level switching applications, and 0.1uF ceramic capacitors as generic IC supply decoupling.

If board space allows, higher priced integrated modules can be replaced by circuitry built from discrete components. Examples include DC-DC converters, FET drivers, and voltage regulators. A direct cost comparison of integrated versus discrete parts can be found in table 2.

Table 2. Example comparison

| Module                                      | Discrete counterpart | Integrated cost | Discrete cost |
|---------------------------------------------|----------------------|-----------------|---------------|
| 12V FET driver (MCP1401)                   | 2 BSS123, 1 BSS84, 3 resistors | $0.5            | $0.12         |
| DC-DC step-up converter (FAN5333)          | diode+ inductor+ caps+ power nFET + MCU PWM + MCU/comparator | $0.4 - $0.5    | $0.1 - $0.5  |

Printed circuit board (PCB) prices largely depend on the size of board, the number of PCB layers and the number of days in manufacture. While it is cost efficient to design a 2-layer PCB, if the design has high speed signals (>10MHz) it is advisable to go for a 4-layer board instead. The reason behind this is that the designer can put the high speed signals on an internal layer that is being shielded by the top and the bottom copper. This greatly helps achieve electromagnetic compatibility compliance.

There is a significant price break on electronic components if they are ordered in high volumes. Therefore the best cost reduction is to produce the devices in high quantities.

Software will be also a critical part of this integrated approach. As explained before, software represents a fixed development cost that is less influential in the overall cost of the planned system design.

It is also favourable for non safety critical systems to allow interaction with general purpose electronic devices commonly found in households, like personal computers or handheld mobile devices. These devices can take the tasks of a remote controller or a data logger, therefore reducing overall system cost. An example of this is the functionality of ThorMed’s Otthon mobile spirometer that is the ability to synchronize device database with a PC to archive data. The contents of the device can be archived directly to ThorSoft Pulmonary Diagnostics PC software. Developing PC software can also be more cost efficient than embedded systems. Also the integration of a printer is not required if the device can connect to any commercially available USB printer and print out reports of current and older measurements.

4.2 Safety concerns of cost reduction

Designing cost effective medical devices does not mean that they do not have to have the same level of functional safety. Most modern medical devices (like for example medical ventilators) are safety critical systems, and therefore should be designed to meet specific safety standards. An overview of specific standards and testing procedures can be found in the work of Fowler (2010.).

As explained in Fowler’s (2010.) work, designing and evaluating safety critical devices means significant work time, and a large part of the overall cost for these devices consists of the testing and verification of safety critical components and functions. Therefore, a significant cost reduction can be achieved by finding a proper partitioning between safety critical and non safety critical components within a specific system. Only the components considered safety critical should be designed and verified according to the specific standards, while other, less critical components can be designed with less expenses and additional cost can be saved on their testing and evaluation. Accurately defining the safety critical parts of a highly integrated system is however not a trivial task and although there are some formal methods, the most part of it must be done intuitively. General rules exist that can help the classification. For example, the user interface is mostly not safety critical. Standalone diagnostic and data acquisition systems are also for the most part not safety critical. However, a processing algorithm of a sensor which’s failure can cause a dangerous situation must be considered safety critical and implemented according to the relevant standards.

5. CONCLUSIONS

The paper presents an overview of the developments in the SINOPOLL project which’s aim is to present modern and affordable means for the practitioners of traditional Chinese medicine. The research and development effort is mainly focused on methods for diagnosing and curing respiratory illnesses like asthma or COPD. As was stated in this paper, the main research areas of this project are the new diagnostic methods, and new treatment or administering methods. It was determined, that most of the modern medical systems can be adapted for use in TCM. Also a significant part of this research and development effort was cost reduction. Using the aforementioned methods and techniques, it was possible to successfully reduce the overall costs of the proposed devices and systems.

The main goal of this ongoing project is to develop a complete diagnostic and administering system for TCM applications. All the technologies related to this work are already commercially available in Thormed’s medical devices. The integration of these technologies for use in TCM is, however, still in the prototyping stage.
The project is still far from completion, but when complete, the resulting methods and implemented devices will also be able to be used as an objective testing and evaluation platform for TCM’s methods. Thus contributing to a better understanding of how its methods work and how efficient they really are.

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