Development TPN Module and Interface for the EasyCompounder

Bachelor Thesis, Industrial Design Engineering at SmartCompounders B.V.

TPN is an abbreviation of “Total Parenteral Nutrition”. The word “parenteral” means: administered elsewhere in the body than through the mouth, alimentary canal and digestive system. So to sum up, TPN is a fluid mixture consisting of all the necessary nutrients, which is stored in an IV bag, so it can be administered directly into the circulatory system (blood veins). The main reason for using TPN is when a patient cannot or should not receive their nutrition through eating. Some examples of situations when TPN is needed are[1]:

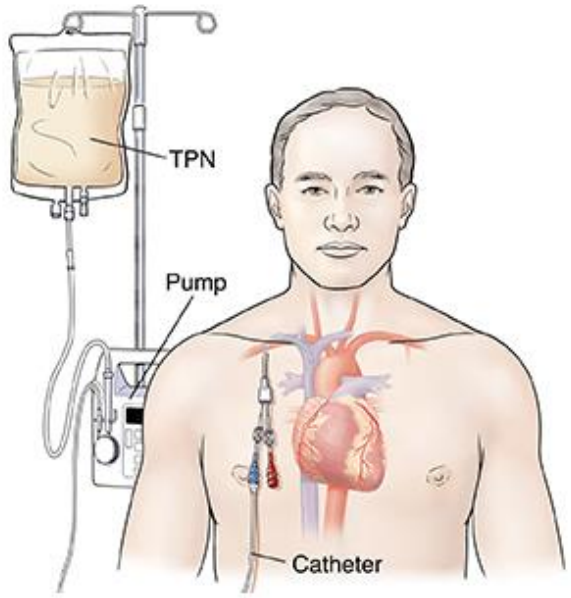

Figure 1 administering of TPN [5]

- Obstructed intestines
- Bowels need to rest (e.g. Chrohn’s disease or pancreatitis)
- Inability to eat (e.g. severe burns or multiple fractures)
- Malnourishment (e.g preparation for major surgery, chemotherapy or radiation treatment)

TPN is created by using a process called “pharmaceutical compounding” and is mainly executed in hospital pharmacies (or compounding centers). Pharmaceutical compounding is the practice in which supplements of a drug or nutrition are combined, mixed or altered to create a medication tailored to the needs of an individual[2].

The supplements, used for each TPN mixture, are roughly the same and consist of around 12 types, but the dosage of each supplement is dependent on for example the age, weight, height and medical condition, of each individual patient. Some examples of the supplement that are used are[2], [4]:

- Carbohydrates (e.g. dextrose)
- Lipids (e.g. fats)
- Amino acids (e.g. protein)
- Electrolytes (e.g. potassium and sodium)
- Trace elements (e.g. zinc and copper)
- Additional components (e.g. vitamins and minerals)

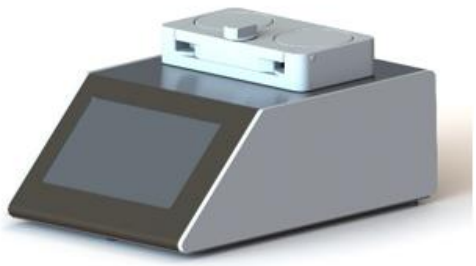
Figure 2 EasyCompounder unit [3]

To be able to dose each individual supplement, a pump is needed. So, what the company SmartCompounders had already developed, was a device called the EasyCompounder. This is an intelligent automated dosing unit, that uses two peristaltic pumps, to accurately compound personalized medication or

nutrition. And onto this unit, several types of modules can be connected, each suitable for a certain type of compounding process (e.g. for filling IV bags, syringes or vials)[3].

Figure 3 schematic representation of a peristaltic pump

Because the compounding of TPN is currently still being done manually or with “outdated” machines, SmartCompounders wanted to develop a new module for this, called the TPN module. What this device needed to do, is bring the previously mentioned supplements together, so they can be automatically mixed and stored in an IV bag. So, within this bachelor thesis, the aim was to further develop the TPN module and to come up with a design for the EasyCompounder’s Graphical User Interface (GUI) (which is needed for operating the device).

After executing some preliminary research, analyzing the results from this research, setting up the list of requirements and generating ideas/concepts, 3D CAD (Computer-Aided Design) models of the pinch valves and TPN module were made in SolidWorks and the GUI menu pages where created in MockFlow. Next up, some of the final concepts are shown and briefly explained.

Pinch valve:

By inserting a tube into the pinch valve and then rotating the DC motor (#1) clockwise or counterclockwise, the in- and outwards movement of the pinch head (#2) can be controlled. And so the tube can be squished and the flow of a fluid can be regulated.

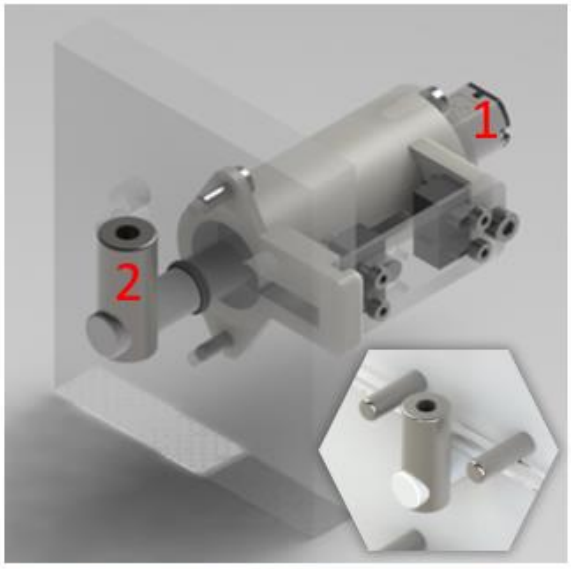

Figure 4 front view of the pinch valve mechanism

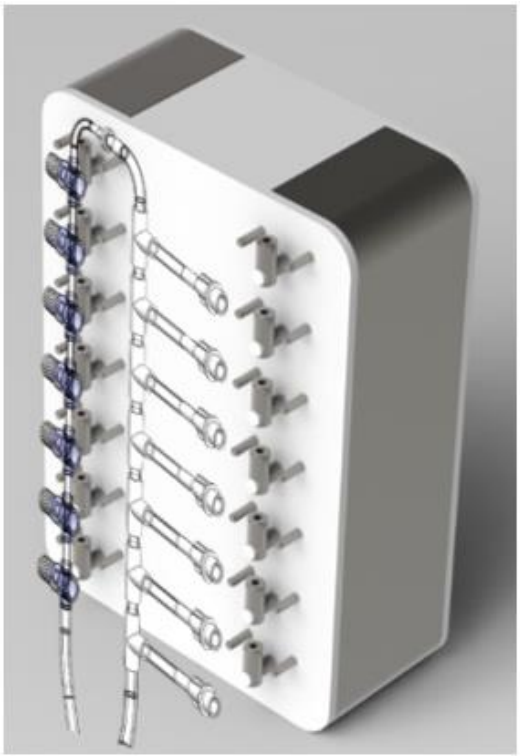

Figure 5 front view of the TPN module, together with a part of the disposable tube set

TPN module:

The TPN module consists of 14 pinch valves, into which a disposable tube set can be inserted. This module is used to control the flow of individual supplements, by closing and opening the tubes. So when closing all the tubes, except one and then start the EasyCompounder pump, a predetermined amount of a certain supplement can be collected from the supplement container (depending on the amount of peristaltic pump rotations) and dispensed into an IV bag.

Internal hardware:

To be able to automatically control each individual pinch valve, microcontroller circuit boards and other hardware components (confidential) are used and placed on the inside of the TPN module. Then by connecting the EasyCompounder to the USB connector on the bottom of the TPN module's back plate, the EasyCompounder touchscreen interface can be used to control the TPN module.

Figure 6 TPN module's internal hardware

Figure 8 overview of the TPN module's GUI menu pages

Graphical User Interface (GUI)

The mockup of the GUI can be used to for example set up the machine, control the automated compounding process, see statistics about preparations, etc.

Additional devices:

To be able to, in the future, quickly scan the preparation ID, supplement container, IV bag and disposable tube set barcodes, a camera module can be added. And to print the labels for the IV bags and supplement containers, a label printer can be added

Figure 7 From left to right: Label printer, EasyCompounder & GUI, barcode scanner

Finally, to test the designs, prototypes of the models were made. First, to check if the pinch valve could completely stop fluids from flowing, the prototype was tested by inserting different diameter tubes, closing the pinch and pumping water through them.

secondly, to check if the pinch valves could be automatically controlled, the prototype of the internal hardware was tested by connecting it to the power grid and laptop.

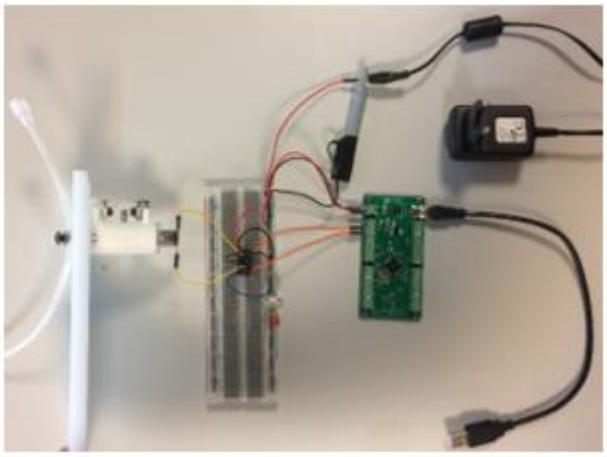

Figure 8 test set-up for the pinch valve and TPN module's internal hardware

Then, to test the GUI, the mockup was displayed on the EasyCompounder's touchscreen and tried out by the hospital pharmacists in Heidelberg.

And finally, the results of all the tests turned out positive and the additional received feedback was used for further improvements.

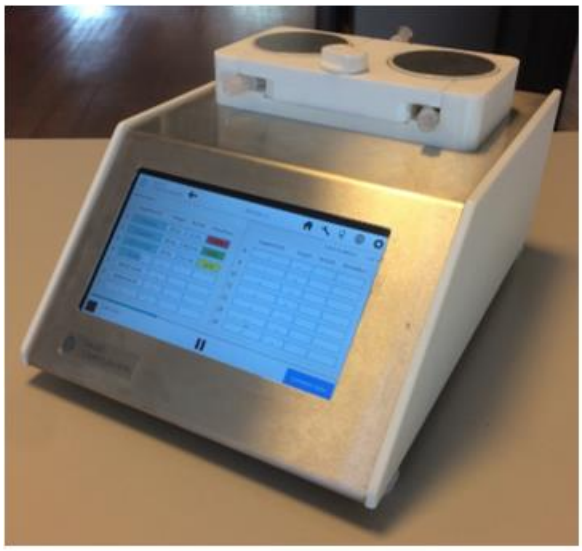

Figure 9 TPN module's GUI, displayed on the EasyCompounder's touchscreen interface

[1] Gastroparesis Patient Association for Cure and Treatments, Inc. (G-PACT). (n.d.). *Total Parenteral Nutrition (TPN).* Retrieved from https://www.g-pact.org/gastroparesis/nutrition/intravenous-nutrition/tpn [Accessed: 2020, April 21]

[2] (2018, June 21). Compounding and the FDA: Questions and Answers. *Food and Drug Administration.* Retrieved from https://www.fda.gov/drugs/human-drug-compounding/compounding-and-fda-questions-and-answers

[3] van Vreeland, S. (n.d.) Automating pharmacy compounding. *SmartCompounders B.V*. Retrieved from https://www.smartcompounders.com/ [Accessed: 2020, April 15]

[4] Thomovsky, E., Reniker, A., Backus, R., Mann, F.A., Dodam, J.R. (2007, February). Parenteral Nutrition: Uses, Indications, and Compounding. *An In-Depth Look: Parenteral Nutrition.* Retrieved from https://www.researchgate.net/profile/Elizabeth_Thomovsky/publication/6113558_Parenteral_nutrition_Uses_indications_and_compounding/links/56bb486008ae0c9607e0900c/Parenteral-nutrition-Uses-indications-and-compounding.pdf

[5] Mount Nittany Health. (2016, January 7). *IV Care Total Parenteral Nutrition TPN Therapy.* Retrieved from https://www.mountnittany.org/articles/healthsheets/4562