Concept Development of Product for Fecal Sample Analysis

Rasmus Olsson & Christian Forsberg
Machine Design, Department of Design Sciences LTH
Lund University
P.O. Box 118
SE-221 00 Lund, Sweden

Abstract

Eurodiagnostica AB is a company that develops, manufactures and markets an extensive product range, such as complete diagnostic kits and reagents for use in medical assessments. At present the company is developing an analysis kit for assaying human stool samples, focusing on detection of the protein Fecal Calprotectin (F-calprotectin). As a complement to this diagnostic kit, the company seeks to develop a discrete product (an "extraction device") that can simplify and streamline the laboratory process behind this analysis.

The goal of this project is to assist Eurodiagnostica AB in developing a competitive extraction device relative a few rivaling alternatives on the market. The contribution to this is in the form of two concepts that seek to meet the business goals of Eurodiagnostica AB and the needs of the user.

Introduction

The analysis of F-calprotectin is an increasingly popular analysis method at hospital laboratories, in Sweden and worldwide. F-calprotectin can be used as marker for several serious chronic gastrointestinal diseases of which can be mentioned IBS, IBD, Crohn's disease and Ulcerous Colitis. [1] By detecting a person's levels of F-calprotectin it is in some cases possible to exclude more expensive and – for the patient – unpleasant diagnostic methods such as colonoscopy. It is also possible and often desirable to follow the development of the aforementioned gastrointestinal diseases over time. The concentration of F-calprotectin is to date expressed in µg/g feces.

In practice, a fecal sample is delivered from the patient to the hospital laboratory in an appropriate container, after which F-calprotectin is extracted through a series of steps. The diagnostic kits delivered by Eurodiagnostica AB and its competitors contain the chemical substances required to perform the extraction process. In terms of this project the goal is to produce a sort of Swiss-army knife for the extraction process, in other words a device that extracts a specific volume of a feces sample, puts the specified volume in contact with an extraction buffer (a part of the diagnostic kit) and facilitates the dissolution of the sample in the buffer.

Regarding the consistency of fecal samples

The project opens up for numerous interesting design issues, with a big part of the problem being the nature of a stool sample as its consistency may differ widely. Developing a product specifies a certain volume of a sample

while taking notice of the different textures which the sample may take is not an easy task.

Initial research

Screening of competitive extraction devices

There are few existent solutions within the market for fecal sample analysis. However, in the field of quantitative analysis, the field in which Eurodiagnostica AB aim to impress, there is in fact only one product competing in the same market segment. Other products within the feces analysis are mostly so-called quick-tests that merely give a qualitative indication of the level of F-calprotectin or other markers. According to Eurodiagnosticas specifications, the future product is also the only one based on measuring volume rather than weight, like the competing products do.

Another important insight from the product screening is that the stool sample is delivered by each patient in a container whose design only differs slightly between different brands. This knowledge will prove to be of significance to the product design. The sample container is represented in Figure 1 below.

Figure 1 – Stool sample container

User studies

A user study is done which points out profits and drawbacks of a range of existing products. Hands-on studies are made to give a better picture of the process and the experience carrying out the extraction. A fair amount of theory surrounding the extraction of F-calprotectin is gone through to be able to put the product in a bigger context.

Based on the user study, target specifications according to Ulrich and Eppinger [2] and an industrial design-style functional analysis are established. The needs of all stakeholders are analyzed and translated into the largest extent possible to features in the product.

The concepts

Basic function

It was early realized that the most convenient way to transfer a piece of sample from the stool sample container (Figure 1), is to use the existent spoon from the container. In that way there is no problem collecting feces, regardless of consistency, and laboratory personnel would not have to put the spoon away after opening the sample container.

Two concepts were delivered to Eurodagnostica. Both concepts are primarily based on the simple idea that, out of a larger piece of sample, we take a smaller amount (20µl). This way, it is assured that we have enough sample material to work with. Figure 2 shows the device after a piece of sample has been transferred from the stool sample container, packed down with the lid causing excess material to be pushed to the sides.

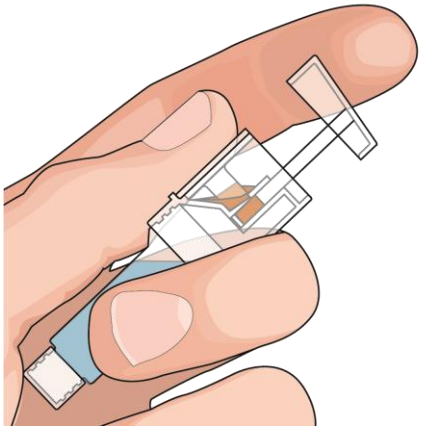

Figure 2

The 20µl of stool is pushed into the extraction buffer and is exposed from both sides, which considerably facilitates the decomposition of the stool sample by the extraction buffer. The result of this step is displayed in Figure 3.

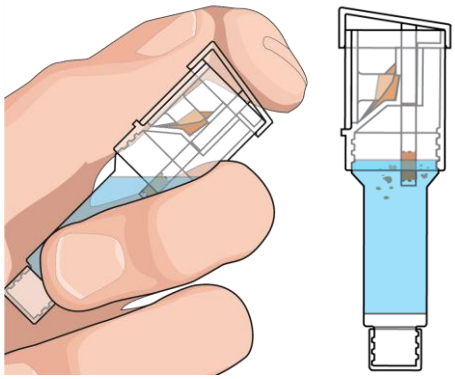

Figure 3

The extraction buffer is contained within the concepts, and may either be buffer from Eurodiagnosticas own kit or that of a competitor. A filter is used to separate unsolved particles from the extract. By pushing the extract through the filter with simple "bottle mechanic" into another container of choice (Figure 4) the extract is ready for further analysis, the latter which explicitly means a spectrophotometric analysis using an ELISA-matrix.

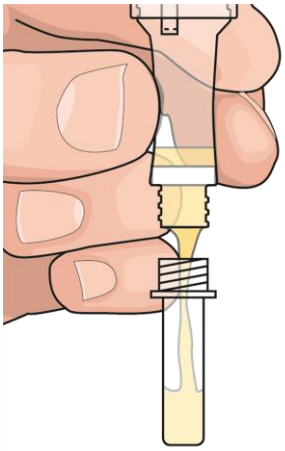

Figure 4

Materials and manufacturing

The material is Poly-Propylene (PP), and there are no requirements of sterility of the product [3]. Both concepts are intentionally simplistic in their designs, optimized in terms of plastic construction and fully possible to manufacture. This straightness is to allow for future development and to give an opportunity to add features rather than having to remove them. An example of this is to be able to add seals to prevent leakage, as no materials other than PP are used. The sealing of the product is a vital feature in case of loose feces and to prevent buffer from transferring between different parts of the extraction device. This can be solved in numerous ways and is a question for further product development.

Conclusion

The biggest gain from the future product will hopefully be a less time-consuming process. This will mean less strain on laboratory personnel as these can spend precious work hours on other tasks. Further, reducing the number of steps in the extraction process will induce smaller environmental

impact by reducing the number of throwaway articles.

The future for this kind of analysis is bright, and Eurodiagnostica AB is on the right track developing a product that offers the above discussed procedure. Apparently, the concepts need refinement and many technical issues are still left unsolved but the concepts are, as mentioned, intentionally stripped-down in their design to allow further improvements and changes. If improving on the concepts generated by this project, small scale tests of the concepts should initially be carried out. These will pin-point their respective strengths and weaknesses, and revisions could be made to the function analysis and target specifications. New features may be added or existent ones may be changed in favor of the product.

List of References

[1] Larsson, Anders (2010). Kalprotektin i feces bra markör för gastrointestinal inflammation. Läkartidningen 43, 2645-2649.

[3] Ulrich, Karl, Eppinger, Steven (2008). Product Design and Development. McGraw-Hill, New York NY, USA

[3] Bruder, Ulf (2011). Värt att veta om plast. Ulf Bruder och Bruder Consulting, Sverige

Pictures

[Figure 1] http://www.promed.ie/shop/catalog/product.aspx?categoryid=2875&serverid=medica