

# P452 Usability study of a smartphone-based patient monitoring system measuring Calprotectin for therapy follow-up

C. Reinhard, J. Weber, C. Niederberger, F. Perretta



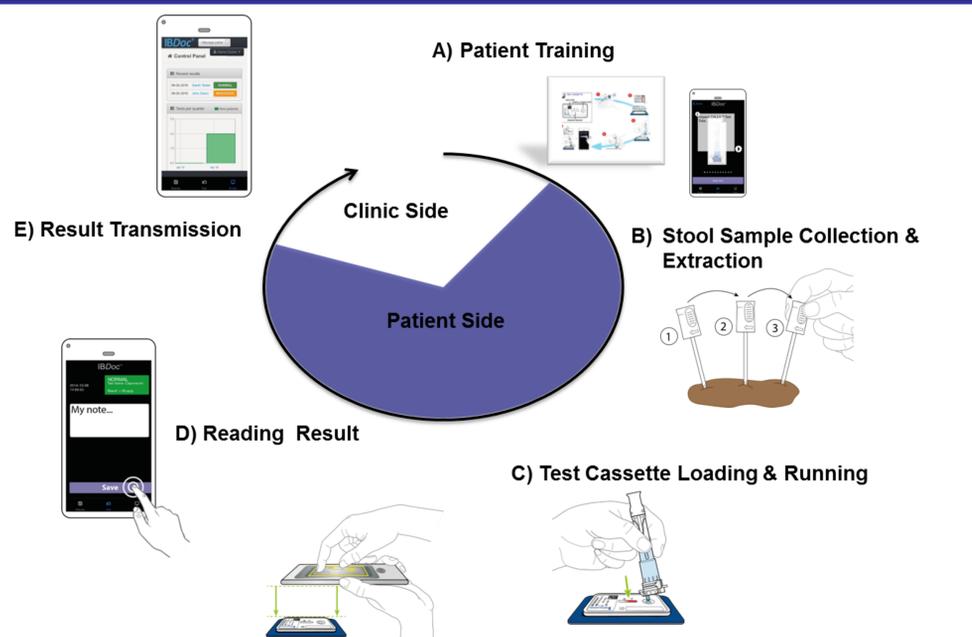
BÜHLMANN Laboratories AG, Schönenbuch, Switzerland (correspondence: cre@buhlmannlabs.ch)

## BACKGROUND

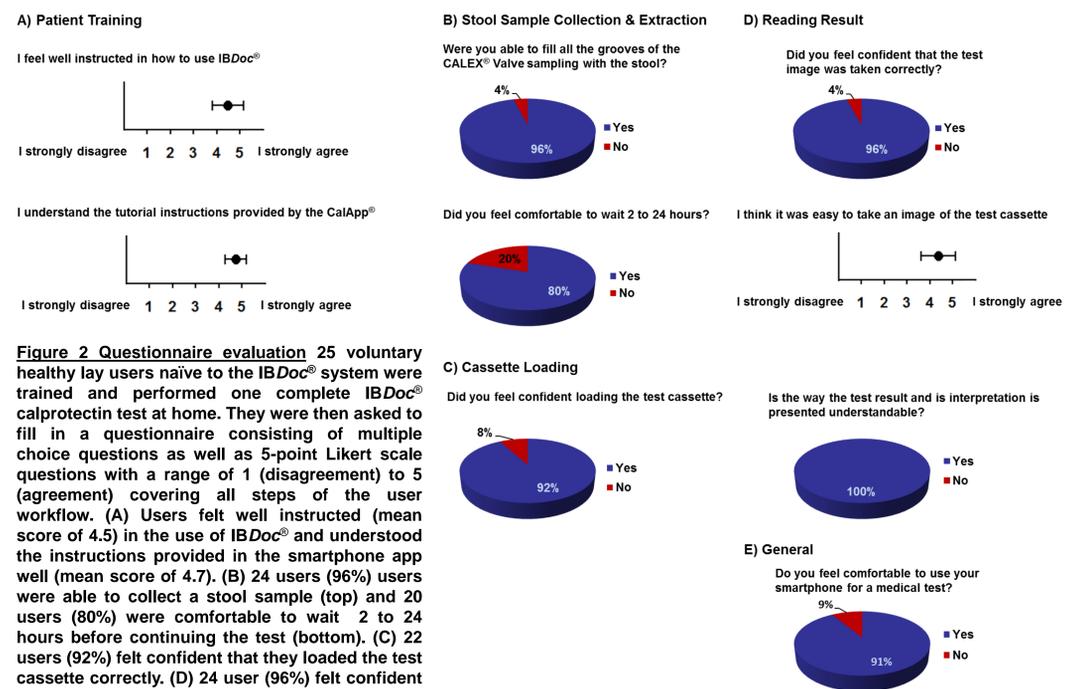
Inflammatory Bowel Disease (IBD) is a chronic inflammation of the gut presenting with phases of active inflammation, remission and relapses. To ensure real-time information about the inflammatory activities in the gut for both, the clinician and the patient, we have developed a calprotectin home test called IBDoc<sup>®</sup>. The IBDoc<sup>®</sup> system consists of a stool collection and extraction device (CALEX<sup>®</sup> Valve) and an immunochromatographic calprotectin rapid test, which is read using a smartphone application (CalApp<sup>®</sup>) controlling the phone's camera. Once the result is calculated by the app it is sent automatically to a webserver (IBDoc<sup>®</sup> Portal). There the treating physician has immediate access to the result. The objective of this study was to evaluate the usability of the IBDoc<sup>®</sup> calprotectin home test system with lay users in respect of handling both, the physical test components as well as the integrated software.

## METHODS

25 voluntary healthy lay users (age 24 - 60 years) naïve to the IBDoc<sup>®</sup> system were trained to perform the test, and then asked to carry out one calprotectin stool test by themselves at home. The lay users were then asked to fill in a questionnaire based on 5-point Likert scale questions, free commentary sections and standardized System Usability Scale (SUS) questions. The SUS score is commonly used in measuring and comparing the usability of software and integrated software systems<sup>[1]</sup>.



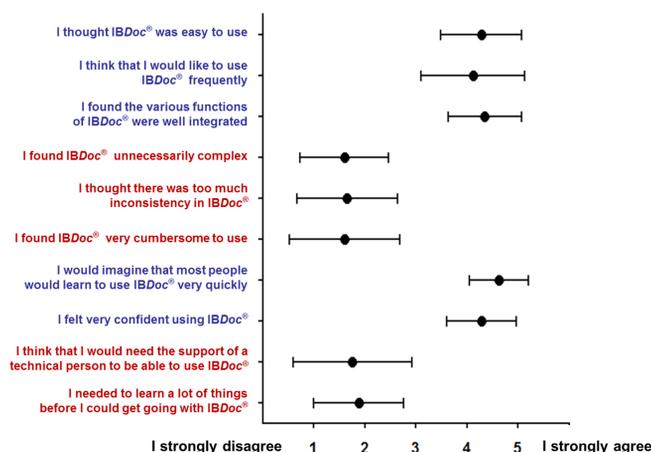
**Figure 1 IBDoc<sup>®</sup> System user workflow** (A) Patients are being initiated and trained by their clinic and receive the test kit to perform a calprotectin test at home. (B) The patient collects stool with the stool collection paper and takes a sample with the sampling pin of the CALEX<sup>®</sup> Valve device containing the extraction buffer. (C) A precise amount of stool sample extract is applied onto the immunochromatographic calprotectin rapid test cassette. (D) After 12 minutes the test cassette is ready and a picture is taken within the CalApp<sup>®</sup> smartphone application. (E) The result is calculated by CalApp<sup>®</sup> and automatically sent via a secure internet connection to the IBDoc<sup>®</sup> Portal database, where it can be accessed and reviewed by the patients treating physician.



**Figure 2 Questionnaire evaluation** 25 voluntary healthy lay users naïve to the IBDoc<sup>®</sup> system were trained and performed one complete IBDoc<sup>®</sup> calprotectin test at home. They were then asked to fill in a questionnaire consisting of multiple choice questions as well as 5-point Likert scale questions with a range of 1 (disagreement) to 5 (agreement) covering all steps of the user workflow. (A) Users felt well instructed (mean score of 4.5) in the use of IBDoc<sup>®</sup> and understood the instructions provided in the smartphone app well (mean score of 4.7). (B) 24 users (96%) were able to collect a stool sample (top) and 20 users (80%) were comfortable to wait 2 to 24 hours before continuing the test (bottom). (C) 22 users (92%) felt confident that they loaded the test cassette correctly. (D) 24 users (96%) felt confident that the picture was taken correctly (top) and judged the process of taking a picture as easy (middle panel, mean score of 4.4). All users (100%) understood the generated result. (E) 21 users (91%) felt comfortable to use their smartphone for a medical test.

## RESULTS

All 25 lay users were able to generate a calprotectin test result by themselves. 24 out of 25 users were able to collect and extract a stool sample with the CALEX<sup>®</sup> Valve extraction device without major problems, and 22 out of 25 were confident that the rapid test was performed correctly. When asked how easy it was to measure the test cassette with the smartphone, the users judged this question with an average score of 4.4 on a 5-point Likert scale. 21 users out of 25 felt comfortable to use a smartphone for a medical test. The IBDoc<sup>®</sup> system reached a mean SUS score of 82 on a scale from 0 to 100 compared to the software industry's average score of 68<sup>[2]</sup>.



**Figure 3 System Usability Scale Score** Healthy lay users naïve to the IBDoc<sup>®</sup> system were trained and performed one complete IBDoc<sup>®</sup> calprotectin test at home. They were then asked to fill in a questionnaire consisting of multiple choice questions as well as 5-point Likert scale questions with a range of 1 (disagreement) to 5 (agreement). The questionnaire included in random order the 10 standardized questions of the Standard Usability Scale (SUS) to score the overall usability of the IBDoc<sup>®</sup> system. Depending on the question a positive response would be either shifted to the left (highlighted in red) or to the right (highlighted in blue). All the answers were then used to calculate the overall SUS score of 82 on a scale of 0 (poor usability) to 100 (very good usability).

## CONCLUSIONS

This usability study shows that calprotectin home testing using a smartphone as measuring system was well accepted among the tested lay users. The complexity of the application is low, the entire IBDoc<sup>®</sup> system can be considered very user-friendly and is easy to handle by lay users without prior knowledge or experience with immunochromatographic rapid tests.

### References:

- Brooke, J. (1996). "SUS: a 'quick and dirty' usability scale". In P. W. Jordan, B. Thomas, B. A. Weerdmeester, & A. L. McClelland. Usability Evaluation in Industry
- Sauro, J., & Lewis, J. R. (2012). *Quantifying the user experience: Practical statistics for user research*. Morgan Kaufmann, Waltham MA, USA.

### Disclosure:

In relation to this presentation, I declare the following, real or perceived conflicts of interest:  
 • This study was supported by BÜHLMANN Laboratories AG