

Goal of study

Aim of this study is to assess the usability of the Medimate to measure lithium in fingerstick whole blood as a point-of-care test at a healthcare clinic and as a self test at home.

This test is part of the larger validation study conducted at home and at physician's office. This validation study is approved by the Medical Ethical Committee Twente in the Netherlands with reference number: NL62392.044.17.

Introduction Medimate

Lithium is globally used to treat and prevent manic or depressive episodes in bipolar disorder. The drug has a small therapeutic window and is potentially a toxic substance. Since differences between therapeutic and toxic levels are small, close monitoring of lithium concentration is required. In general monthly controls are recommended or in case of a stable lithium level at least two times a year [1]. However, during the settling time of medication and under irregular or special conditions monitoring of lithium level is required more often.

The Medimate is primarily intended to assess the lithium concentration in blood. Figure 1 shows how a measurement is performed. Specifications of the Medimate are given in table 1. In addition, the Medimate is able to perform a quality control of the applied blood sample due to its ability to detect hemolysis.

Study design

Two tests were performed that included a questionnaire about usability; a point-of-care test (PoCT) at a healtcare clinic and a selftest at home.

PoCT at healthcare clinic

Nurse practitioners of the mental healthcare clinic in Eindhoven were requested to test the performance of the Medimate at the clinic. This involved three measurement series, wherein each serie covered five different days of three consecutive lithium measurements. For each lithium measurement a fingerstick sample was obtained. Furthermore, nurse practioners were requested to fill in a questionnaire about the usability of the Medimate.

Selftest at home

Nine subjects were requested to test the performance of the Medimate under home conditions. The subjects were requested to perform at home three measurements within an hour for five different (not necessarily consecutive) days. The subject was allowed to use a familiarization period. Furthermore, subjects were requested to write down the results on a form after doing a measurement and fill in a questionnaire about usability.

Acceptance criteria

To monitor the usability of the Medimate the scoring system usability scale (SUS) was used. The SUS yields a single number representing a composite measure of the overall usability of the system being used [2], wherein 0 and 100 indicate respectively the worst and best possible outcome with respect to the usability of the system. The SUS can be obtained using a simple ten-item scale. It has proved to be a valuable, robust and reliable evaluation tool [2]. An SUS score above 68 is considered above average [3].

[1] Richtlijn lithium, kenniscentrum Bipolaire Stoornissen (KenBiS),

[2] Brooke, John. "SUS-A quick and dirty usability scale." Usability evaluation in industry 189.194 (1996): 4-7.

[3] Sauro, Jeff. "Measuring usability with the system usability scale (SUS)", MeasuringU, (2011)

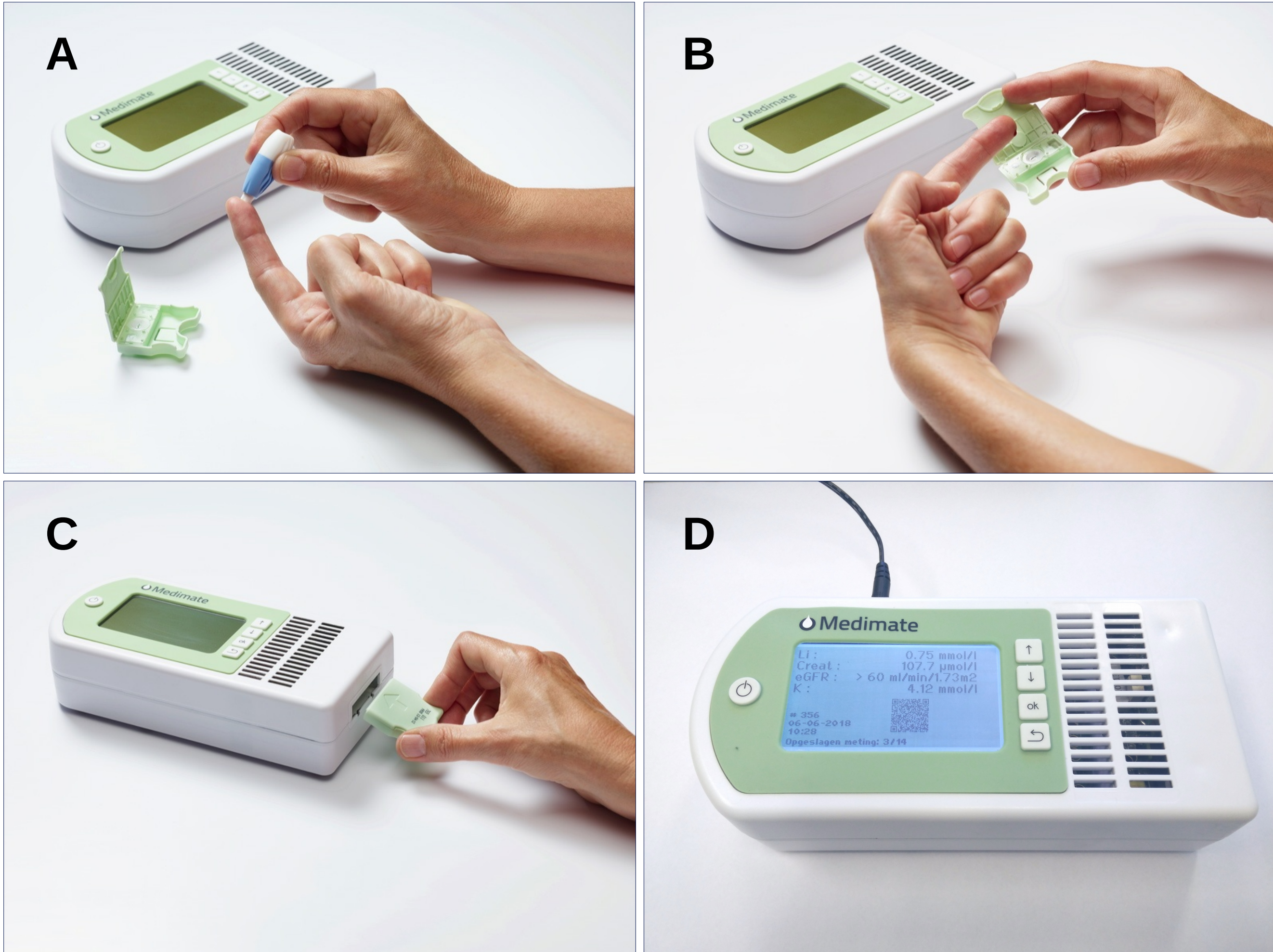


Figure 1: Measurement steps. **A.** Perform fingerstick, **B.** Apply blood droplet on cartridge, **C.** Insert cartridge, **D.** Readout result after 8 minutes

Table 1: Specifications of Medimate

Medimate	Analytes	Samples	Users
<ul style="list-style-type: none"> Multireader (reusable measurement apparatus) Lab-chip (disposable cartridge) 	<ul style="list-style-type: none"> Lithium Potassium Creatinine 	<ul style="list-style-type: none"> Fingerstick whole Blood Venous serum Venous whole blood 	<ul style="list-style-type: none"> Healthcare professionals (point-of-care) Lithium users (self-test)

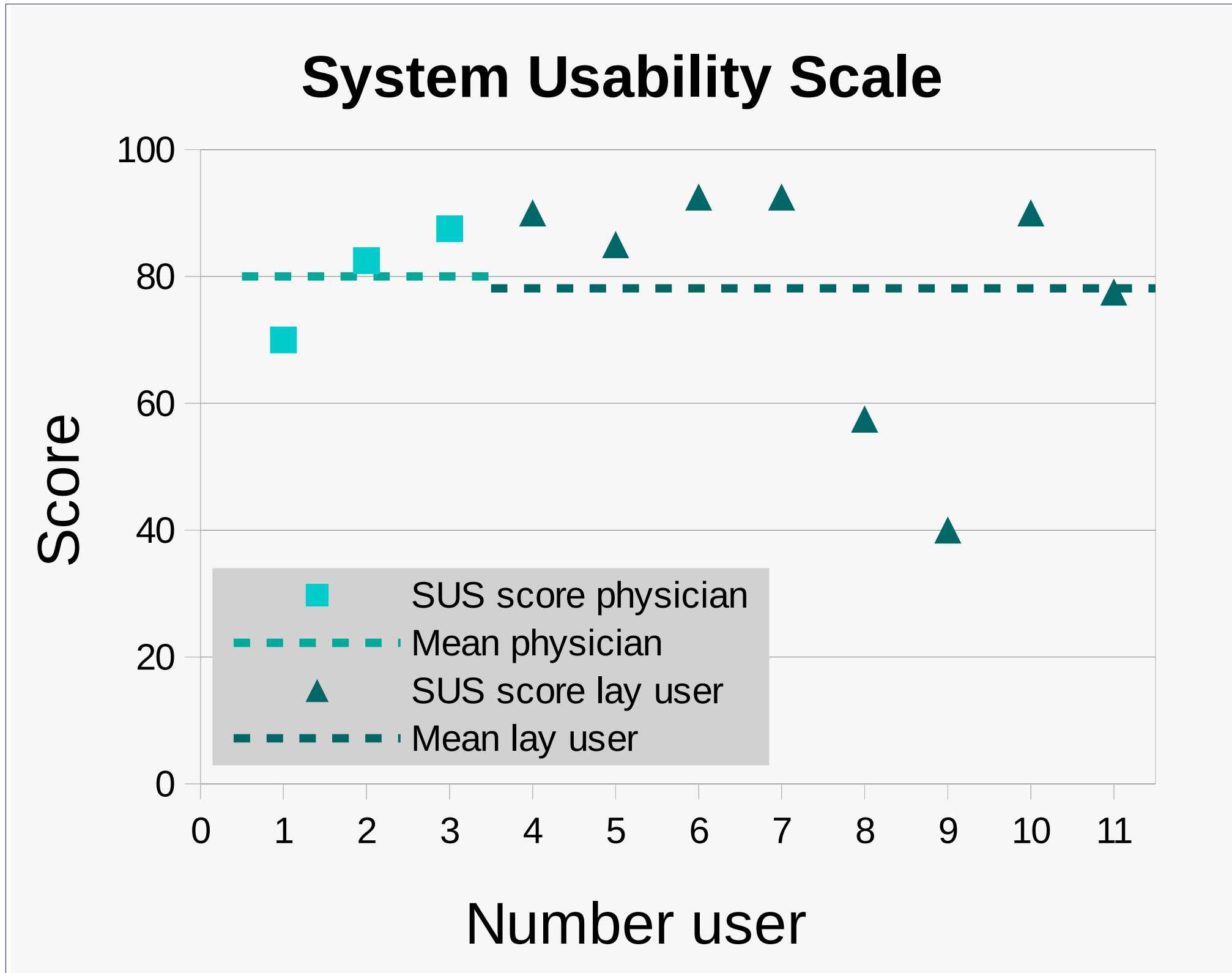


Figure 2: Results outcome System Usability Scale. The SUS scores of three physicians and eight lay users are shown.

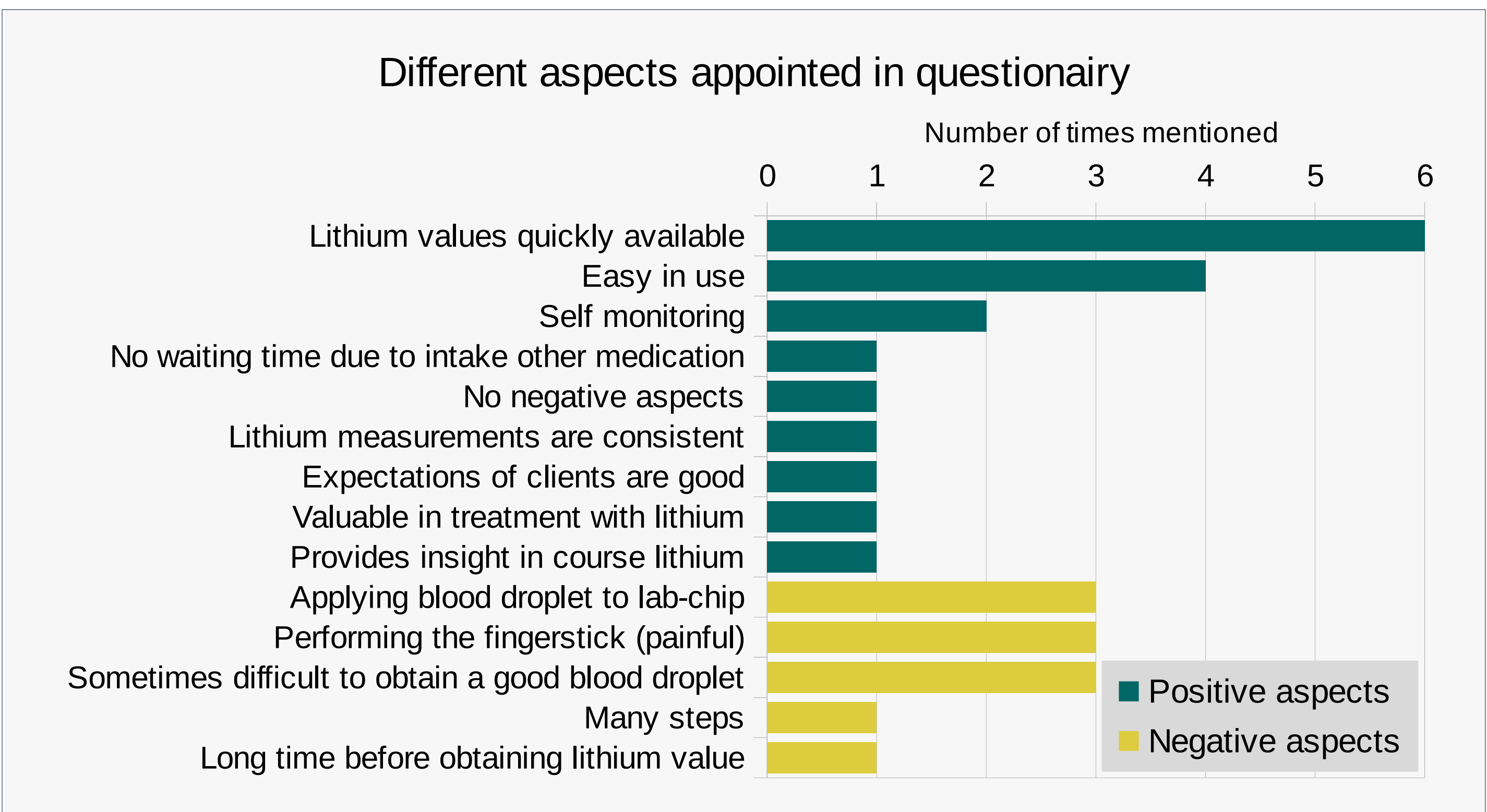
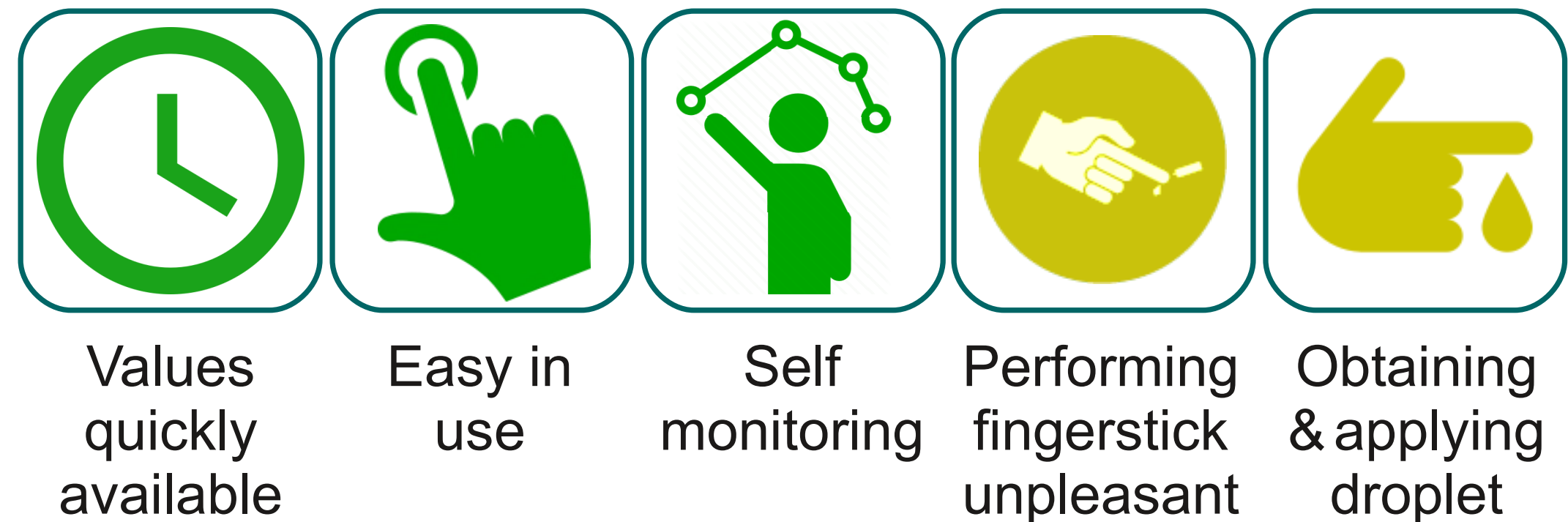


Figure 3: Results outcome questionnaire: positive and negative aspects with respect to usability of the Medimate. The different aspects appointed here by physicians and lay users were answers to the open question: ‘What is the most positive and most negative aspect of the lithium test method based on your experience?’

Results

Nurse practitioners gave an average SUS score of 80 and the subjects gave an average SUS score of 78, see figure 2. One subject was excluded due to recovering from a hypomanic episode. Various aspects about the usability of the Medimate were appointed in the questionnaire and are shown in figure 3.

The positive and negative aspects that were addressed most often were:



In addition, subjects described the Medimate as ‘a good system’. Nurse practioners mentioned they have become more familiar with using the medimate.

Furthermore, questionnaires were completed about the structure, explanation, readability and the completeness of the manual. Nurse practitioners and subjects gave an average score of respectively 72 and 71 on a scale of 0 to 100. Herein, 0 and 100 represents respectively the lowest (worst) and highest (best) score. The manual was clear, but a bit too elaborated.

Conclusions

The usability of the Medimate to measure lithium in fingerstick whole blood, with an SUS score of 80 and 78 of respectively nurse practitioners and subjects, shows very good results for testing at a healthcare clinic and at home. The usability of the Medimate is good for testing at healthcare clinic by nurse practitioners and for testing at home as a selftest.

The support from the European program EFRO via Interreg V program CrossCare is greatly acknowledged.