# Usability Medimate to measure lithium in fingerstick whole blood as self test

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## Goal of study

Aim of this study is to assess the usability of the Medimate to measure lithium in fingerstick whole blood as a self test at home and to assess if the on line module 'Lemli' contributes to self management.

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 the 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. The automatic analysis of fingerstick whole blood within 8 minutes enables self monitoring and is therefore expected to improve self management in combination with the on line platform 'Lemli'. 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

Thirteen subjects were requested to test the performance of the Medimate under home conditions. The subjects were requested to perform at home at least two measurements a week for six different (not necessarily consecutive) weeks. Furthermore, subjects were requested to upload their results to an on line platform (Lemli) using a QR-code.

Afterwards, subjects were invited for an open interview. On the basis of a topic list direction was given to the interview. These topics were about (i) the Medimate, (ii) the on line module, (iii) self management and (iv) the practitioner. Interviews were audibly recorded and transcribed verbatim. After every two interviews a data analysis was performed based on the seven steps of Colaizzi as described by Polit & Beck [2].

## 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 [3], 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 [3]. An SUS score above 68 is considered above average [4].

[1] Richtlijn lithium, kenniscentrum Bipolaire Stoornissen (KenBiS),
[2] Polit, D. F., & Beck, C. T. (2012). Nursing research: Generating ans assessing evidence for nursing practice (9e ed.). Philadelphia, PA: Wolters Kluwer Health/Lippincott, Williams & Wilkins.
[3] Brooke, John. "SUS-A quick and dirty usability scale." Usability evaluation in industry 189.194 (1996): 4-7.
[4] Sauro, Jeff. "Measuring usability with the system usability scale (SUS)", MeasuringU, (2011)

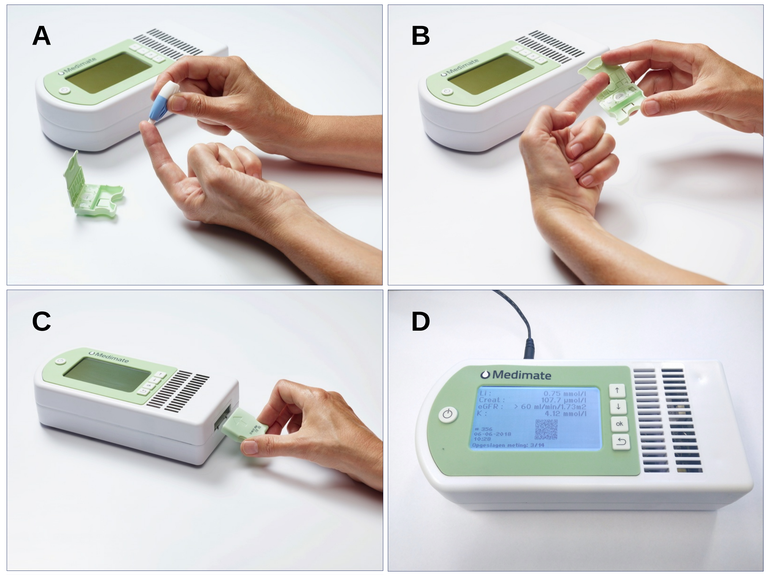



**Figure 1:** Measurement steps: **A.** Perform fingerstick, **B.** Apply blood droplet on cartridge, **C.** Insert cartridge, **D.** Readout result after 8 minutes and scan QR-code to upload results to on line module, **E.** Gain insight into the course of the lithium level using the on line module 'Lemli'.

**Table 1:** Specifications of Medimate

| Medimate | Parameters | Samples | Users |
|---|---|---|---|
| • Multireader (reusable measurement apparatus)<br>• Lab-chip (disposable cartridge) | • **Lithium**<br>• Potassium<br>• Creatinine | • Fingerstick whole Blood<br>• Venous serum<br>• Venous whole blood | • Healthcare professionals (point-of-care)<br>• Lithium users (self-test) |

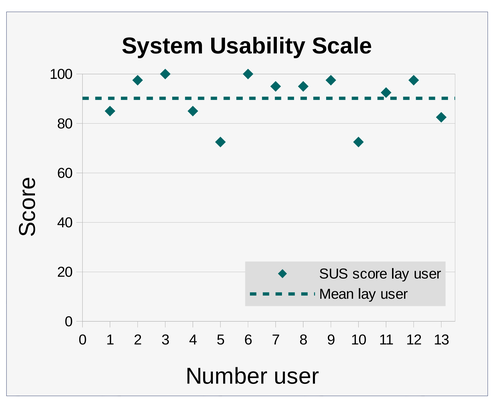



**Figure 2:** Results outcome System Usability Scale.
The SUS scores of thirteen subjects are shown.



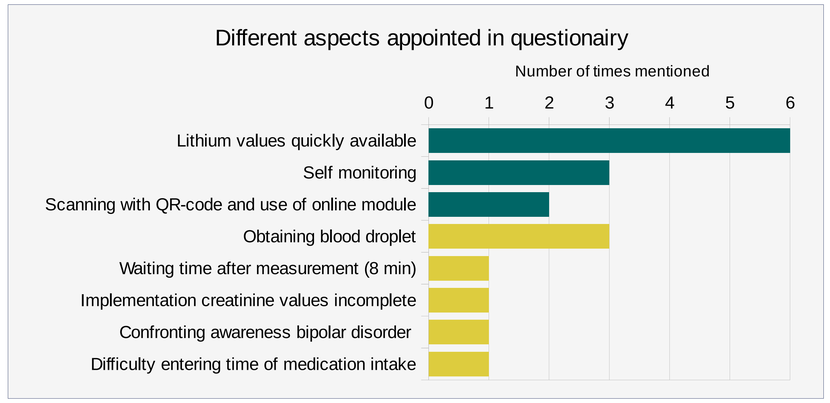
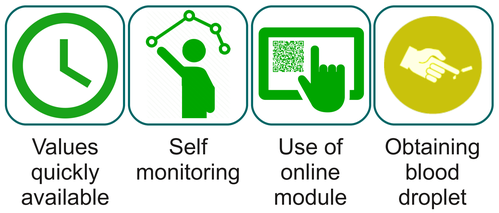



**Figure 3:** Results outcome questionnaire: positive and negative aspects with respect to usability of the Medimate. The different aspects appointed here by lay users were answers to the open question: 'What is the most positive and most negative aspect of the lithium test method based on your experience?'

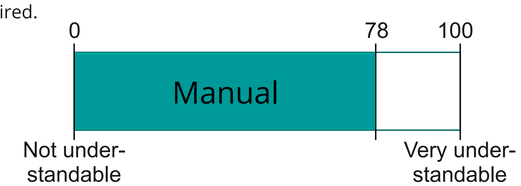
## Results

Subjects gave an average SUS score of 90, see figure 2. 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 more than once were:




Furthermore, questionnaires were completed about the structure, explanation, readability and the completeness of the manual. Subjects gave an average score of 78 on a scale of 0 to 100. Herein, 0 and 100 represent respectively the lowest (worst) and highest (best) score for understandability. Especially the quick guide was appreciated. In general the manual met the requirements of lay users. However, more information about the interpretation of the blood values was desired.




## Conclusions

The usability of the Medimate to measure lithium in fingerstick whole blood, with an SUS score of 90 from subjects, shows excellent results for testing at home. The usability of the Medimate is good for testing at home as a self test

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