Blood Glucose Systems

Typical protocol (A)
Capillary samples from diabetes and healthy individuals were collected in a hospital laboratory. Each sample was determined in duplicate by instrument and designated reference method. In addition a sample for hematocrit was taken. Then some capillary samples were measured in duplicate by intended users in the primary care centres. Three different lots of test strips were used. The evaluators answered questionnaires about the user-friendliness of equipment.
Typical protocol (B)
Only diabetes patients took part in the evaluation. Half of the participants had two consultations and the rest of them had one consultation. The diabetes patients in the “training group” were given a standardised instruction about the insturment before they did a finger prick and performed two measurements on the meter. The biomedical laboratory scientist also collected capillary samples from the diabetes patients and measured twice. In addition, two capillary samples were taken for measurements with a designated comparison method. The diabetes patients in the “mail group” received the equipment by mail and no training was given. Both groups of diabetes patients used the equipment for approximately three weeks at home, before they attended for a final consultation. The blood glucose sampling and measurement procedures at the first consultation were repeated, and in addition a sample for hematocrit was taken. Three different lots of test strips were used in the evaluation. All the participants answered questionnaires about the user-friendliness and the user guide of equipment.
Typical protocol (C)
Only diabetes patients took part in the evaluation. All the diabetes patients had two consultations. The diabetes patients were given a standardised instruction about the instrument and did a few finger pricks to get to know the instrument. The diabetes patients used the equipment for approximately two weeks at home, before they attended for a final consultation. At this consultation the diabetes patients did a finger prick and performed two measurements on the meter. The biomedical laboratory scientist also collected capillary samples from the diabetes patients and measured twice on equipment. In addition, two capillary samples were taken for measurements with a designated comparison method. In addition a sample for hematocrit was taken. Three different lots of test strips were used in the evaluation. All the participants answered questionnaires about the user-friendliness and the user guide of equipment.
Typical protocol (D) (supplementary evaluation)
All diabetes patients that took part in the supplementary evaluation participated in the previous evaluation of the instrument where they were trained in how to use the meter. In this supplementary evaluation the diabetics received the equipment by post and no new training was given. After approximately one week they came for a consultation. The diabetics did a finger prick and performed two measurements on the meter. The biomedical laboratory scientist also took capillary samples of the diabetic patients and measured twice at instrument. In addition, two capillary samples were taken to a designated comparison method. In addition a sample for hematocrit was taken. Three different lots of test strips were used in the evaluation. All the participants answered questionnaires about the user-friendliness and the user guide of equipment.

Typical protocol (E) (under optimal conditions and by persons with diabetes)
Approximately 90 persons with diabetes were included in the evaluation. All participants received the device and instructions by mail and no training was given. After approximately two weeks of using the device at home, the participants attended an evaluation meeting. At the evaluation meeting, fresh capillary whole blood samples from each participant were analysed on the evaluated system under both optimal conditions by a biomedical laboratory scientist and under real-life conditions by the participants. Three lots of test strips were used. Capillary plasma samples from the same individuals were analysed on a comparison method (a glucose hexokinase method). In addition, a venous sample for haematocrit was taken from each participant. For evaluation of user-friendliness and the user-manual of the equipment, all participants answered a questionnaire.
Typical protocol (F) (under optimal conditions)
Approximately 90 persons, preferably persons with diabetes, were included in the evaluation. Fresh capillary whole blood samples from each participant were analysed on the evaluated system under optimal conditions by a biomedical laboratory scientist. Three lots of test strips were used. Capillary plasma samples from the same individuals were analysed on a comparison method (a glucose hexokinase method).