ADDIS ABABA UNIVERSITY

COLLEGE OF HEALTH SCIENCES

SCHOOL OF ALLIED HEALTH SCIENCE

DEPARTMENT OF MEDICAL LABORATORY SCIENCES

Comparison of SensoCard Glucometer versus Routine Clinical Chemistry Analyzer Humastar80

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A Research thesis submitted to the Department of Medical Laboratory Sciences, School of Allied Health Science, College of Health Science, Addis Ababa University, in partial fulfillment of Master of Science Degree in Clinical Laboratory Sciences (Clinical Laboratory Management and Quality Assurance specialty track).

June, 2016.

Addis Ababa, Ethiopia.

Addis Ababa University

School of Graduate Studies

This is to certify that the thesis prepared by Rediet Debesom, entitled:

"Comparison of SensoCard glucose meter versus routine clinical chemistry analyzer Humastar80 at Mettu Karl Hospital south west-Ethiopia" and submitted in partial fulfillment of Master of Science degree in Clinical Laboratory Science (Laboratory Management and Quality Assurance Specialty Track) complies with the regulations of the University and meets the accepted standards with respect to originality and quality.

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ACKNOWLEDGEMENT

I would like to thank my advisor Dr. Mistire Wolde for his valuable and close follow up. I owe a huge debt of gratitude to those volunteer study participants. I also thank Addis Ababa University, graduate school for the financial support of this thesis project. Moreover, my family and my friends, your courage and moral made me to reach at this level, and so truly appreciate your efforts. And I wish also to express my appreciation to Mettu Karl Hospital staffs for their warm hospitality.

In general, I thank you all who were so generous with their time and expertise, and support my thesis work directly or indirectly from inceptions up to where it is now.

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List of Abbreviations

BG	Blood Glucose
CE	ConformitéEuropéenne
CI	Confidence interval
DC	data collector
DM	Diabetes Mellitus
FAD	Flavin Adenine Dinucleotide
FC	FerroceneCarboxylate
GOD	Glucose oxidase
ISO	International organization for standardization
MDI	Multiple dose insulin
PI	Principal investigator
POC	Point of care
POD	Peroxidase
SMBG	Self monitoring blood glucose
SPSS	Statistical package for social science
4AAP	4 Amino-antipyrene

Abstract

Background: Diabetes mellitus (DM) is a chronic disease which requires continuing medical care and ongoing patient self-management. SensoCard is one of pocket Glucose meter devices used to measure blood glucose for screening and monitoring diabetes mellitus.

Objective: The aim of this study was to assess the accuracy of the cheapest and more available POCGD SensoCard glucose meter by comparing with conventional clinical chemistry analyzer HumaStar80 at Mettu Karl hospital.

Methods: Data's on commercially available POCD, with respected to price and sustainable supply of test strips were collected by pre-tested questioner, from March 1 to March 30, 2015 in Addis Ababa. A total of 170 importers and wholesalers were interviewed during the study period. Then hospital based cross-sectional study was conducted from April 2015 to June 2016, to assess accuracy sensocard PoCGD compared with conventional Clinical chemistry test analyzer-Humastar80 at mettu karl hospital, southwest Ethiopia. A total 50 Diabetic patients was participated in the study. Glucose value was determined by glucose oxidase methods in both SensoCard glucose meter and the glucose oxidase HumaStar80 as a reference in the present study. The data was entered and analyzed by SPSS version 20.The minimum accuracy of Sensocard was determined in both based on ISO 15197:2003 and ISO 15197:2013 criteria. Correlation coefficient and bias was calculated to observe the agreement of the glucose meter result with the comparative method.

Result: From 148 of importers only 12 of them import glucose meters from different countries like India, Thailand, Singapore and Turkey. Of the available PoCGD, "sensocard" was relatively cheapest and had sustainable supply by the importers. On the accuracy assessment of "sensocard" PoCGD versus conventional human star80 clinical chemistry glucose test results,
Twenty three (46%) participants were females. The mean age of the study participants were 49.29 ±12.96.The mean serum glucose value measured by reference method was 242.96 ± 102.4 mg/dl and where as that of SensoCard glucose meter was 236.76 ± 92.6 mg/dl. There was no statistically significant difference between the means of SensoCard glucose meter and reference method glucose value (p-value=0.084). The correlation coefficient between the two methods was 0.862. The SensoCard glucose meter underestimated the overall glucose value from the reference

method glucose value by a bias of 6.22. Moreover, SensoCard test result compared with reference method, were expected to be within 95-100% ranges, nevertheless this cant's happened. Therefore SensoCard test measurements did not fulfill the minimum accuracy requirements of ISO 15197:2003 and ISO15197:2013.

Conclusion and recommendation: Although "sensoCard PoCGD was cheap and had more supplies in the market, its measurement lack accuracy as compared with reference conventional chemistry methods. Further study should be undertaken including hypoglycemic and normoglycemic individuals in addition to DM patients to justify the present findings.

Keywords: point of care glucose meter, Sensocard, Humastar80

1. INTRODUCTION

1.1. Background

Diabetes mellitus (DM) is a metabolic disorder resulting from a defect in insulin secretion, insulin action, or both. Insulin deficiency in turn leads to chronic hyperglycemia with disturbances of carbohydrate, fat and protein metabolism [1]. It is also a condition primarily defined by the level of hyperglycemia giving rise to risk of micro vascular damage like retinopathy, nephropathy and neuropathy. And, macro vascular complications like ischemic heart disease, stroke and peripheral vascular disease which are cause of reduced life expectancy, significant morbidity and diminished quality of life [2].

DM is one of a chronic disease which requires continuing medical care and ongoing patient self-management education and support to prevent acute complications and to reduce the risk of long-term complications. Patients of DM should do self-monitoring of blood glucose (SMBG) at least prior to meals and snacks, occasionally post prandially, prior to exercise, at bedtime, when they suspect low blood glucose, after treating low blood glucose and prior to critical tasks such as driving[3]. Self-monitoring blood glucose systems have the potential to play an important role in the control of diabetes and in the reduction of risk of serious secondary clinical complications [2].

Diabetes care is complex and needs multi factorial risk reduction strategies to glycemic control in both the hospital and outpatient settings [3]. By using dry and wet chemistry we can diagnose the value of glucose in blood [4].

Wet chemistry is a term that represents a number of scientific techniques that involve direct experimentation with liquids. Because it is a broad industry term, the exact definition can vary from business to business. A general rule that can be applied is that if it involves a scientist working with liquids by hand and physically observing the results of the experiment, it is wet chemistry. The use of robotics in the laboratory, however, has even challenged this definition to some extent. This type of chemistry includes basic experimentation techniques like measuring, mixing, and weighing chemicals, as well as testing concentration, conductivity, density, pH,

specific gravity, temperature, viscosity, and other aspects of liquids. Example; HumaStar80, BioSystem A25 Chemistry Analyzer spectrophotometer, etc [4].

Dry chemistry refers to a diagnostic format where a test pad is bonded to support structure such as plastic strip for ease of handling the test pad for exposure to the test sample and read out. The test pad is impregnated with an analyte which when exposed to test sample will change color or some other property which can easily be seen or measured with a reader. Example; urine strips, Self-monitoring of blood glucose, etc [4].

In addition to the important role above, Point-of-Care (POC) testing have an advantage like reduced therapeutic turnaround time of diagnostic testing, reduced preanalytic and postanalytic testing errors, rapid data availability, self-contained and user-friendly instruments, shorter patient length of stay, small sample volume for a large test menu, convenience for clinicians and ability to test many types of samples[5].Various POC tests have been found to be non-inferior to laboratory testing for managing chronic conditions in general practice and aboriginal medical services [6]. Self-monitoring of blood glucose (SMBG) with glucose monitoring systems is widely recognized as an integral component of adequate diabetes management that enables patients to control their blood glucose (BG) levels effectively [7,8].

There are many types of glucose meters and few of them also available in Ethiopia like Accu-check active,one touch select simple, gluco one BG03, SensoCard glucose meter etc, for blood glucose monitoring. The use of them in DM patients is increasing from time to time [9] SensoCard glucose meter is advanced biosensor technology size of 55x90x7mm and it weighs 64g. It measures glucose levels even in 0.5µL blood with in 5seconds, this glucose meter analysis applies the enzyme glucose oxidase and is based on advanced electromechanical technology that is specific for β-D glucose measurement specifically catalyzes glucose and reduces interferences. Its measuring range is 20-600 mg/dl concentration of glucose. It works in an optimum temperature of 10-40°C. The meter stores the last 500 results in its memory [10-12].

HumaStar80 is automated clinical chemistry batch analyzer which has the ability to run up to 80 tests per hour with 20 reagent and 54 sample positions, and also have 144 cuvette capacity to load and computer. The machine use reagents like Glucose liquicolor which uses enzymatic colorimetric test, GOD-PAP method and Glucose liquiUV^{mono} which uses hexokinase method

mono reagent with absorption of (500,546nm) and (334,340,365nm) respectively[13].Therefore, the aim of this study is to assess the accuracy of SensoCard glucose meter comparing with HumaStar 80 conventional clinical chemistry analyzer as measured by GOD-PAP.

1.2. Statement of the problem

International Diabetes Federation Atlas (IDFA) in 2011 estimated 366 million people suffer from DM and the number is expected to rise to 552 million by 2030.Most of this increase will occur as a result of 150% rise in developing countries. It is estimated that developing countries will bear the brunt of DM epidemic to the extent of 77% of the global burden in the 21st century as a result of population growth, ageing, unhealthy diets, obesity and sedentary lifestyles [14].

In sub-Saharan Africa 10.8 million people have DM in 2006 and that this would rise to 18.7 million by 2025, an increase of 80%, as such exceeding the predicted worldwide increase of 55% [14]. In Ethiopia national data on prevalence and incidence of DM are lacking. However, patient attendance rates and medical admissions in hospitals are rising [15]. In addition IDFA reported Ethiopia to be ranked 3rd among the ten top countries in Africa with 1.4 million DM cases and estimated prevalence of 3.32% by year 2012[16].

IDF estimates that as many as 175 million people worldwide, or close to half of all people with diabetes, are unaware of their disease[14].The earlier a person is diagnosed and management of diabetes begins, the better the chances of preventing harmful and costly complications like micro vascular damage like retinopathy, nephropathy and neuropathy. Increase risk of macrovascular complications like ischemic heart disease, stroke and peripheral vascular disease which could be the cause of reduced life expectancy, significant morbidity, diminished quality of life and finally death. The need to diagnose and provide appropriate care to people with diabetes is therefore urgent [14].

The worldwide market for SMBG is $2.7 billion per year, with annual growth estimated to be 10–12%, this show that there are many types of glucometers exist in global market and many patients and health facilities use SMBG[8]. Here in Ethiopia there are 258 drug and medical supplies importer and wholesalers import and distribute different kinds of glucose meter that

varies in cost and manufacturer (16). Because of this many patients and health facilities are facing difficulties what to choose? And why? [16].

Despite this fact, correlation of blood sugar result produced by SMBG when compared with wet chemistry machine results, some discrepancies has been recorded. Study conducted in Germany, 2009-2010 indicate out of 34 BG systems assessed only 18 (52.9%) of 34 systems fulfilled the minimal accuracy requirements of the current draft revision of ISO 15197[8] , whereas another an evaluation study published in 2010 showed that more than 40% of the systems investigated did not fulfill the minimum accuracy criteria of the ISO standards[17]. Therefore, in order to get reliable and good correlated results between SMBG and wet chemistry machine results, regular monitoring and evaluation of test results produced by these two machines are mandatory. Thus here we focused on the assessment of Sensocard, a type of SMBG machine results versus wet chemistry (HumaStar80) results, in order to have accurate results. Since inaccurate systems bear the risk of false therapeutic decisions [14].

1.3. Significance of the study

On top of the fact that there are various glucose meters in global market[8] and also presence of few of them in national market[16] assessing the most cheapest and sustainable supply of test strips will help to guide the users. Mettu Karl Hospital is referral hospital for Illubabor Zone and Gambella region serves approximately 50,000 patients per year. So providing a quality service in this hospital assures health of peoples while ensuring efficient use of resources.

Many diabetic patients and health facilities use SMBG to monitor blood sugar. It is also recommended to improve metabolic control for patients with diabetes because tight glycemic control can decrease complications in individuals with diabetes [8]. Since inaccurate systems bear the risk of false therapeutic decisions. The accuracy of measurement of blood glucose is imperative for the reliability of results and, finally, the medical outcome in diabetes therapy. Therefore, evaluation of BG meters and test strips should be done in order to ensure adherence to accuracy and quality standards [8].

There are many diabetic patients and health facilities uses self monitoring blood glucose to monitor blood sugar and there are different kinds of glucose meters in the market [16]; knowing which to choose depending on cost, availability, easy maintenance and mostly easy to operate is mandatory.

1.4. Literature reviews

Studies done by IDF shows Diabetes mellitus (DM) is unanimously recognized as one of the principal healthcare epidemics of the 21st century [18–19]. Such remarks stem from epidemiological data highlighting the rising burden of DM as shown by the prevalence of DM increasing from 285 million to 382 million between the years 2011 and 2013 [20-21]. Although such figures are themselves alarming, what is even more disconcerting is that this inexorable increase will culminate with DM representing the 7th leading cause of mortality by the year 2030. Realizing the gravity of the situation, augmented by the lack of an existing definitive treatment, healthcare systems have invested heavily in measures to dampen the ramifications of the diabetes epidemic. Although the principle areas of expenditure are predominantly in the management of diabetic complications and diabetic medications, another area with significant investment is in glucose monitoring systems that aid in the self-monitoring of blood glucose (SMBG) [22].

Numerous studies have shown that SMBG provides an effective means of controlling blood glucose (BG) levels so it is widely recognized as an integral component in the management of DM [22]. By providing instantaneous feed back to the user, in the form of their current BG level, patients can achieve effective glycemic control whilst ensuring rapid identification of BG levels that require immediate emergency intervention [22].Moreover, rigorous control of BG levels has demonstrated a significant reduction in the development of debilitating complications which are known to reduce the quality of life. Reflecting the necessity of SMBG, various organizations such as the National Institute of Health and Clinical Excellence (NICE) and the American Diabetes Association (ADA) regard the SMBG as an integral feature in the management of Dm

[23].

Self-monitoring of blood glucose (SMBG) with glucose monitoring systems is widely recognized as an integral component of adequate diabetes management that enables patients to control their blood glucose (BG) levels effectively [24,25]. Several studies have demonstrated that tight BG control is essential for diabetes patients to avoid late complications [13,26, 27]. The clinical benefits of SMBG in diabetes patients are widely accepted, and today, SMBG is

recommended for all people with diabetes, particularly for adjustment of insulin in patients with multiple daily injections [26].

A multitude of SMBG systems is available on the market. An increasing number of new systems have been introduced. Therefore, Physicians and patients are looking for guidance to choose between systems with different price ranges, including well-established systems as well as completely new systems, e.g., systems providing new technologies [28].

The accuracy of a SMBG measurement is imperative for the reliability of results and, finally, the medical outcome in diabetes therapy. DIN EN ISO 15197:2003 is an internationally accepted standard defining performance requirements for BG systems for SMBG, e.g., concerning accuracy.

The standard states that ≥95% of the BG system measurement results shall fall within ±15 mg/dl of the results of the manufacturer's measurement procedure at glucose concentrations <75 mg/dl and within ±20% at glucose concentrations ≥75 mg/dl. A revised version of the International Organization for Standardization (ISO) standard, expected to be published in 2012, includes tighter criteria for the minimum accuracy of BG systems [29]. The current draft revision of ISO 15197 states that≥95% of the system measurement results shall fall within ±15 mg/dl of the results of the manufacturer's measurement procedure at glucose concentrations<100 mg/dl and within ±15% at glucose concentrations≥100 mg/dl [8].

So The minimum acceptable accuracy for results produced by SensoCard glucose meter according to ISO 15197:2003, is: ≥95% of the individual glucose results shall fall within ±15 mg/dl of the results of the manufacturer's measurement procedure at glucose concentrations <75 mg/dl and within ±20% at glucose concentrations ≥75 mg/dl and according to ISO 15197:2013, is: ≥95% of the individual glucose results shall fall within ±15 mg/dl of the results of the manufacturer's measurement procedure at glucose concentrations <100 mg/dl and within ±15% at glucose concentrations ≥100 mg/dl [12,13]

However, an evaluation study published in 2010 showed that more than 40% of the systems investigated did not fulfill the minimum accuracy criteria of the ISO standard [17]. Study conducted in Germany, 2009-2010 indicate out of 34 BG systems assessed 27 (79.4%) of systems fulfill the minimal accuracy requirements of the standard DIN EN ISO 15197:2003.

Only 18 (52.9%) of 34 systems fulfilled the minimal accuracy requirements if tighter criteria of the current draft revision of ISO 15197 are considered. Because inaccurate systems bear the risk of false therapeutic decisions, regular and standardized evaluation of BG meters and test strips should be requested in order to ensure adherence to quality and accuracy standards [8].

In another study which was conducted in two family practice residency sites in Ohio where 111 patients were observed testing their blood glucose values on their own glucose monitors,53% of patient glucose values were within 10% of the control value, 84% were within 20% of the control value, and 16% varied 20% or more from the control value. Two patients had dangerously inaccurate glucose determinations [30].

The study which was conducted in Countess of Chester Hospital NHS Foundation Trust (CoCH), Cheshire, United Kingdom at 2014 to Evaluate the GlucoRx Nexus Voice TD-4280 Blood Glucose Monitoring System's Accuracy, failed to adhere to the minimum accuracy requirements stated in the ISO 15197:2003 guidelines, despite the manufacturer claimingotherwise and the BG meter being awarded the CE mark [31].

In another study conducted in Frankfurt in 2012 out of 18 BG systems assessed 13 (72.22%) of systems fulfill the minimal accuracy requirements of the standard DIN EN ISO 15197:2003. Only 10 (55.55%) of 18 systems fulfilled the minimal accuracy requirements if tighter criteria of the current draft revision of ISO 15197 are considered [3].

In study conducted in USA 2013, about validity and reliability of a glucose meters against industry reference standards, found that the portable glucose meters had poor validity and reliability compared to the benchmark laboratory analyzer. Furthermore, glucose readings from the glucose meter showed fixed and proportional bias [32].

In another study conducted in south Africa in 2012 six glucose meter compared with clinical chemistry analyzer, 75% the glucose meters fulfill the minimal accuracy requirement of old version of DIN EN ISO 15197:2003. Only two of them full fill the recent draft version of ISO15197 [33].

In study conducted in Tanzania in May 2012 shows out of 13 glucose meters imported from different countries only 7 of them full fill both the current and the oldest DIN EN ISO 15197:2003[34]

In the study conducted here in our country Ethiopia Gondar University on sensocard by using BioSystems A25 Chemistry Analyzer spectrophotometer as reference, The SensoCard glucose meter and the reference glucose oxidase methods showed a good correlation of 0.975 in determining blood glucose concentrations. In addition, there was no statistically significant difference between the means of blood glucose values between the two methods. However, SensoCard glucose meter underestimate blood glucose value averagely by 3.59 from reference glucose oxidase method. Moreover, the SensoCard glucose meter did not fulfill the minimum accuracy requirements of ISO 15197:2003 and ISO 15197:2013 [9].

2. OBJECTIVE

2.1 General Objective

- To compare blood glucose values determined by SensoCard glucose meter(77 Elektronika Kft., Budapest, Hungary) and HumaStar80 clinical chemistry analyzer(Ref 16880 Human, Germany).

2.2 Specific objective

- To assess most available, cheapest and easy to use glucose meter.
- To assess the correlations of blood glucose measurement done by HumaStar 80 and SensoCard glucose meter.
- To assess whether sensocard fulfill minimum accuracy requirements of ISO 15197.

2.3 Hypothesis

- There is a correlation between Humastar 80 and sensocard glucose meter.
- Sensocard glucose doesn’t full fill ISO minimum requirements.

3. MATERIALS AND METHODS

3.1. Study Design and Period

Data's on commercially available POCD, with respected to price and sustainable supply of test strips were collected by pre-tested questioner, from March 1 to March 30, 2015 in Addis Ababa. A total of 170 importers and wholesalers were interviewed during the study period.

A cross-sectional study, questioner and laboratory based study was conducted from May – June 2016,

3.2 Study site

Since Addis Ababa is the capital of the nation's 92.7% of importers and wholesalers located here in the town [16].

Mettu Karl Hospital (MKH) is located in Oromia region Illubabor Zone. The hospital was build by Karl Heinz BÖm in 1987 EC. The hospital provides a first level referral treatment and is open 24 hours for emergency services.MKH offers diagnosis and treatment to approximately 50,000 patients a year.

This study site is selected to be MKH because of the felt responsibility of the hospital laboratory and Diabetic clinic to contribute to the quality of laboratory service offered in the hospital, which is the referral center for patients in the zone and Gambella region. It is also a practical attachment site for Mettu University Health science students. The hospital has Humastar80 clinical chemistry analyzer and uses sensocard glucose meter to measure glucose values.

3.3. Study population

Source of population

Drug and medical supplies importers in Addis Ababa. All diabetes mellitus patients who came at the hospital for follow up and patients come for glucose measurements.

3.4 Eligibility criteria

3.4.1 Inclusion criteria

- Drug and medical supplies importers and wholesalers that import and distribute glucose meter who volunteered to fill the questioner.
- Diabetes mellitus patients who were volunteered, who have normal hematocrit value.

3.4.2 Exclusion criteria

- Drug and medical supply importers and wholesalers who were not volunteered to fill the questioner and who doesn't import and wholesale any glucose meter.
- Diabetic mellitus patients who were not on medication like vitamin C and Acetaminophen which has potential to affect glucometer measurement.

3.5. Sample size

- Volunteered 164 importers and wholesalers were participated.
- The clinical and laboratory institute (CLSI) 2011 guide line recommends a minimum of 40 samples for method comparison; in this study a total of 50 were analyzed in duplicates on each instruments to improve the confidence statistical estimates.

3.6. Study variables

3.6.1 Dependent variable

- Blood glucose values

3.6.2 Independent variable

- Humastar80
- SensoCard glucose meter
- Sex
- Age

3.7. Data Collection

Questioner was used to collect data from importers and wholesalers of Drug and Medical equipments.

After demographic information including sex and age were collected by using data abstracting sheet. Blood samples were collected from capillary of finger and ante cubital vein after overnight fasting (12-16hr).Tourniquet was applied for less than one minute, for vein puncture and the sites of blood collection was cleaned by 70% alcohol. The venous blood samples were taken to the laboratory and were centrifuged at 500 g for 5 minutes to obtain the serum. All measurements were done according to the manufacturer's instructions. Capillary blood glucose were determined by SensoCard glucose meter (77 ElektronikaKft, Budapest, Hungary) and venous blood glucose was measured by humastar80 (Ref 16880 Human, Germany). Also venous blood was used by SensoCard to observe the result difference between the one that was performed by recommended sample (capillary blood).

3.8. Principle of Sensocard glucose meter

The Sensocard sensor is constructed on electrodes and uses GOD enzyme and ferrocenecarboxylate (Fc) mediator to carry electrons from GOD to electrode. Flavin adenine dinucleotide (FAD) is used as a coenzyme during the enzymatic reaction. The produced current

under the applied electric voltage is measured by amperometr and then converted to glucose concentration. The intensity of formed electrons is directly proportional to glucose concentration [9].

3.9. Principle of Humastar80 Clinical chemistry analyzer

Glucose is oxidized by glucose oxidase (GOD) enzyme to produce gluconate and hydrogen peroxide (H_2O_2). The H2O2 is then oxidatively coupled with 4 amino-antipyrene (4-AAP) and phenol in the presence of peroxidase (POD) enzyme to yield a red quinoeimine dye that is measured at 500 and546 nm with a colorimetric (Humastar clinical Chemistry analyzer). The absorbance at 500 and 546 is proportional to concentration of glucose in the sample. The method has linearity from 0.0126 mmol/l (0.23 mg/dl) to 27.5 mmol/l (500 mg/dl).

$$\text{Glucose} + 2H_2O + O_2 \xrightarrow{\text{GOD}} \text{Gluconate} + H_2O_2$$
$$2H_2O_2 + \text{4-AAP} + \text{Phenol} \xrightarrow{\text{POD}} \text{Quinoeimine Dye} + 4H_2O$$

Absorbance of the colored solution is directly proportional to the glucose concentration when measured at (500 and546) nm [10].

3.10. Quality assurance

The questioners collected were examined if it is filled correctly or not.

To get reliable data laboratory personals were strictly followed standard operating procedure and manufacturer’s manual during pre-analytical, analytical and post- analytical phases. Reagents and strips were checked for their expiry dates. Reagents diluted or prepared according to manufacturer’s instruction. Control samples were used for reference method of glucose oxidase(HumaStar 80).

3.11. Accuracy evaluation

Accuracy evaluation on questioners collected was done by making sure that every questions were filled correctly and precisely.

At the study site, we tested the participants' fingertip blood glucose with the SensoCard and ante cubital vein blood glucose with HumaStar80 clinical Chemistry Analyzer, which served as the reference. Accuracy were evaluated using International Organization for Standardization (ISO) 15197:2003 and ISO 15197:2013 requirements by calculating the percentage of meter results falling within ±5%, ±10%, ±15% and ±20% of the reference value for glucose concentrations ≥75 mg/dl and ≥100 mg/dl and within ±5, ±10, ±15 and ±20 mg/dl of the reference value for glucose concentrations <75 mg/dl and <100 mg/dl. The minimum acceptable accuracy for results produced by SensoCard glucose meter according to ISO 15197:2003, ≥95% of the individual glucose results shall fall within ±15 mg/dl of the results of the manufacturer's measurement procedure at glucose concentrations <75 mg/dl and within ±20% at glucose concentrations ≥75 mg/dl and according to ISO 15197:2013, is: ≥95% of the individual glucose results shall fall within ±15 mg/dl of the results of the manufacturer's measurement procedure at glucose concentrations <100 mg/dl and within ±15% at glucose concentrations ≥100 mg/dl [10,11].

3.12. Statistical analysis

The data was checked for cleanness and completeness before analysis. The data was entered on spread sheet of Excel and imported for analysis to Statistical Package for Social Sciences (SPSS) version 20 (IBM Statistics, USA).The XLSTAT software was used to plot Bland- Altman graph that used to see the agreement of SensoCard glucose meter with reference spectrophotometric glucose oxidase method in measuring blood glucose concentration. Correlation coefficient and regression line was used to observe the degree of association of the SensoCard with the reference method. T-test was also be used to compare the glucose concentration among varies groups and categories of participants. P-Value <0.05 was considered to be statistically significant at 95% confidence interval (CI).

3.13. Ethical clearance

The study was ethically clear from the Research and Ethical Committee of Addis Ababa University College of medicine and health science School of medical Laboratory Sciences. Data was collected after written consent is obtained from the study participants. To keep confidentiality, non-identifier codes were used and unauthorized person could not able to access the data.

3.14. Dissemination of result

The finalized paper will be submitted to Department of Medical Laboratory Sciences, Addis Ababa University and Mettu Karl hospital. The work will be presented and defended in public. The result will also be disseminated through publication in peer reviewed local or international journal and through presenting it in relevant workshops and seminars.

4. Result

4.1. Cost and availability of glucose meters in market

In Ethiopia there are 258 drug and medical supplies importer and wholesalers from these 148(57.36%) are drug and medical supplies importers and 110 (42.64%) are drug and Medical supplies wholesalers. Most of importers that is 239 (92.6%) and wholesalers located and the rest are in Oromia region mostly in Adama [16]. All of (57.36%) drug and medical equipment importers are also wholesalers.

From 148 of importers only 12 of them import glucose meters from different countries like India, Thailand, Hungary and Turkey. 33.33% from india,25% from Thailand,16.67% from Hungary and 25% Turkey. They import and distribute glucose meters currently like Accu-check active, Foracare voice, Gluco one BG03, Ok Biotech, One touch select simple, Progidy, Sensocard, Taidoc Technology and etc.

The 98% of companies' special reasons for importing those glucose meters is business profit related like cheaper offer, already doing another business and etc. only 2% depend on quality and brand of the glucose meter, in this case all of them are special order from customer.

As more than 80% of wholesalers mentioned costumers usually order or ask for most frequently available glucose meters because they get test strips easily; because of the regular appearance in the market spare parts are easy to get and technicians become familiar with the equipments to operate and maintain.

All of the importers get the supplies from the manufacturers and all of the wholesalers get the supplies in our case the glucose meter from the importers.

But only 67.6% importers distribute the glucose meter to wholesalers door to door, 32.4% of importers let the wholesalers know that the glucose meters are available and the wholesalers collected for themselves. After the wholesalers took over the equipment 49% of the customers (drug stores, health care providers) collect glucose meters for themselves the other 51% of distribution done by the wholesaler itself.

Regularity or sustainable supply of the glucose meters depend on the capital of the importers and currency exchange system of banks. All importers agree that regularity of imported equipments 70% depend on the capital of the company.

As long as there is capital to afford the imported goods regular flow of equipments are granted other than 30% factors that hinder regularity of the glucose meter like; shortage of currency exchange from birr to Dollar or required currency and transport barriers.

Table 1 Cost of glucosemeters and their test strips.

No.	Name of the glucose meter	Cost of single glucose meter	Cost of single pack of test strip
01	Accu-check active	475.00	130.00
02	One touch select simple	455.00	120.00
03	Gluco one BG03	510.00	185.00
04	Tai doc technology	490.00	135.00
05	Ok Biotech	485.00	130.00
06	Sensocard	410.00	100.00
07	Progidy	470.00	140.00
08	Forecare voice	500.00	180.00
09	ReliOn	570.00	240.00
10	I-sens	630.00	290.00
11	Diacure	520.00	190.00hh
12	Novapex	480.00	126.00

From the twelve glucose meter importers only one of them that is 8.33% import glucose meters 4 times in a year, it is the company or importer that import Sensocard glucose meter.

Twice a year 7 of importer that is 58.33% and 4 of importer that is 33.33% import annually. They put this irregularity of equipment flow from manufacturer to the user because of low capital.

From the twelve imported glucose meters 41.66% (5) have expense of greater than five hundred birr and their test strips are more expensive than that of the rest seven glucose meters.

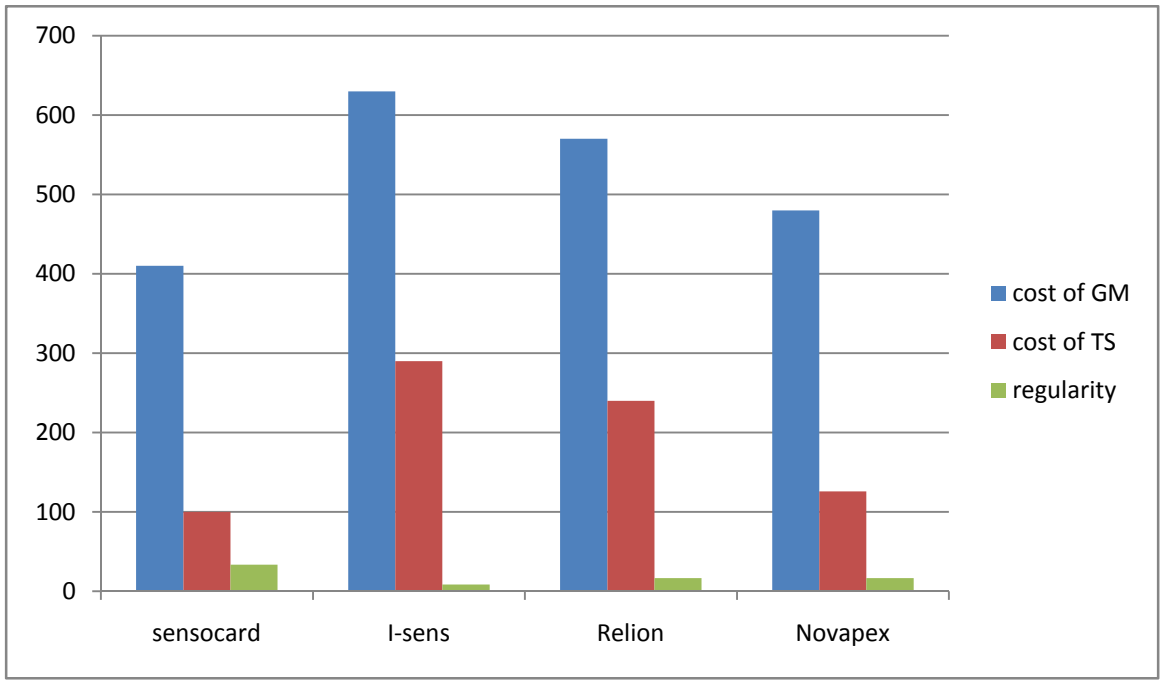

Figure 1. cost of GM , cost of test strips and regularity of five selected GM.

4.2. Sensocard glucose meter versus Humastar80 conventional clinical chemistry analyzer

A total of 50 DM patients were included in this study. Of these, 46% (23) were females. The mean age was 52.28±12.959 ranges 12-73years. The mean serum glucose value measured by glucose oxidase Humastar80 242.96±102.4mg/dl which ranges 62.4-556.3mg/dl and the mean capillary blood glucose value measured by sensocard glucose meter 236.74±92.6mg/dl which ranges 70-512mg/dl. There was no statistically significant difference between the means of sensocard glucose meter and the reference glucose oxidase glucose value (p value=0.084). The bias of sensocard glucose meter was 6.22 and the strength association (correlation coefficient) between the two methods was 0.862 Table2.

The mean difference (bias) between the two methods was not associated with sex and age.However, the mean bias showed statistically significant association with glucose value. The

mean bias increases as glucose value increase in both methods (p-value <0.0012 and 0.015 for glucose oxidase method and SensoCard method, respectively).

Table 2: General characteristics of the two methods' glucose value of patients at Mettu Karl Hospital Illubabor, Ethiopia, 2015.

Parameters	**Sensocard method**	**Glucose oxidase (humastar80)**
Minimum	70	62.4
Maximum	512	398.3
Mean	236.74	242.96
Standard deviation	92.6	102.4
Coefficient of variation (%)	4.722	5.142
Difference between means (bias)	6.22	
p- value	0.084	
95% Confidence interval	-0.3532 to 8.1473	
Correlation coefficient	0.862	

The slope of the regression line for reference glucose oxidase method versus SensoCard glucose meter glucose values was 0.89 with a positive intercept of 9.6 mg/dl. Under simultaneous equation Y=0.89x+9.6 graphs meet at 87 mg/dl glucose concentration. According to the equation, the SensoCard glucose meter overestimated the glucose concentrations below 87 mg/dl and underestimated glucose concentrations above 87 mg/dl.

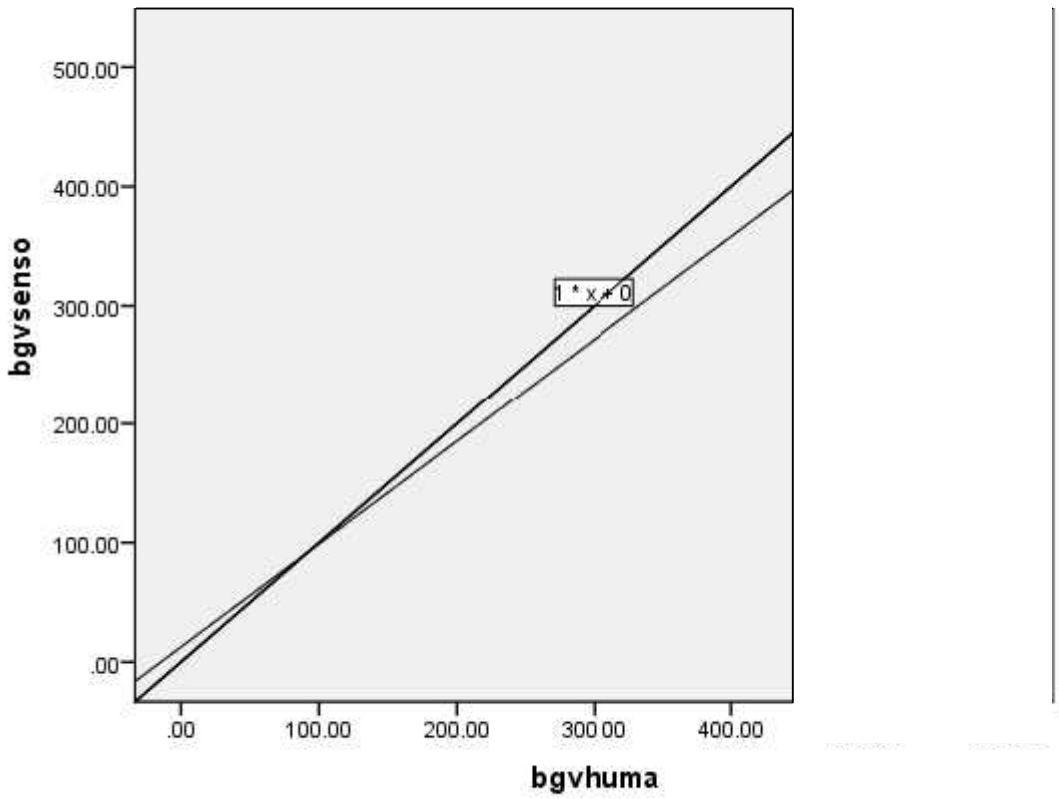

Figure 2,linear regration graph of reference glucose oxidase Humastar80 versus Sensocard glucose meter glucose value of DM patients at Mettu Hospital,illubabor, Ethiopia,2015.

The Bland-Altman plot showed that most of the difference (bias) glucose values between SensoCard glucose meter and reference glucoseoxidase methods lay within the bias ±9.8SD (95% CI). The 95% limit of agreement was -0.3532 to 8.1473.

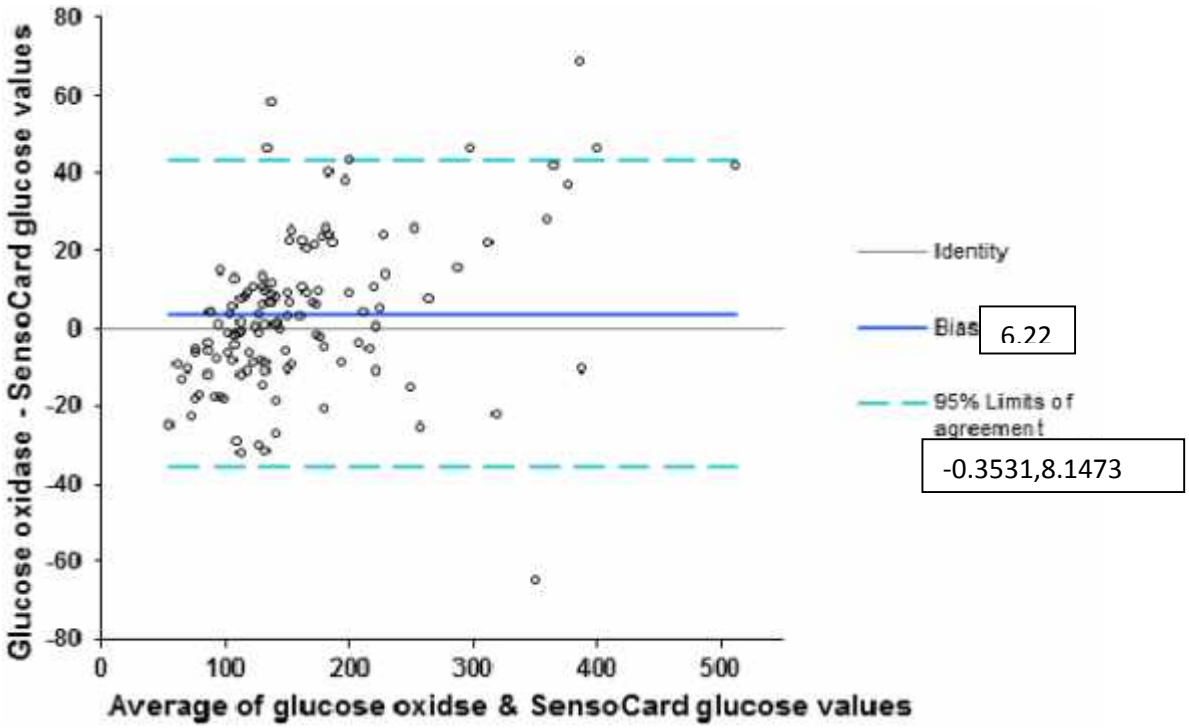

Fig3, the bias plot (Bland altman of plot) of diabetic mellitus patients glucose value between sensocard glucose meter and reference glucose oxidase method(humastar 80) at Mettu Karl Hospital.

The percentage of SensoCard blood glucose values within different deviation ranges of glucose oxidase reference method is shown below.

Table 3: Percentage of SensoCard glucose meter results falling within various intervals of the reference glucose oxidase glucose value of DM patients at Mettu Karl Hospital, Illubabor, Ethiopia, 2015.

Cut point of the reference method	Percentage of SensoCard glucose levels within the reference method intervals				
	Within ± 5%(5 mg/dl)	Within ± 10%(10 mg/dl)	Within ± 15%(15 mg/dl)	Within ± 20%(20 mg/dl)	Beyond ± 20%(20 mg/dl)
<75 mg/dl	0/3(0%)	0/3(0%)	1/3(33.33%)	2/3(66.67%)	1/3(33.33%)
≥75 mg/dl	15 /47(31.9%)	22/47(46.8%)	31 /47(65.95%)	42/47(89.4%)	5/47(10.6%)
Over all	15/50(30%)	22/50(44%)	32/50(64%)	44 /50(88%)	6 /50(12%)
< 100 mg/dl	3/10(40%)	5/10(50%)	6/10(60%)	8/10(80%)	2/10(20%)
≥100 mg/dl	11/40(27.5%)	17 /40(42.5%)	26 /40(65%)	37/40(92.5%)	3 /40(7.5%)
Over all	14/50(28%)	22/50(44%)	32/50(64%)	45/50(90%)	5/50(10%)

NB; For glucose concentrations <75 and <100 mg/dl, the % meter results within ± the specified mg/dl of the reference glucose values are tabulated. For glucose concentrations ≥75 and ≥100 mg/dl, the % meter results within ± the specified % of the reference glucose values are tabulated.

According to ISO 15197 standards, SensoCard results within ±20, ±15, ±10, and ±5 mg/dl of the reference results at blood glucose concentrations <75 and <100 mg/dl and SensoCard results within ±20%, ±15%, ±10%, and ±5% of the reference results at blood glucose concentrations ≥75 and ≥100 mg/dl are calculated (Table 3).

5. DISCUSSION

In Ethiopia there are 258 drug and medical supplies importer and wholesalers from these 57.36% are drug and medical supplies importers and 42.64% are drug and Medical supplies wholesalers. The companies' special reasons for importing those glucose meter 98% of business profit related like cheaper offer, already doing another business and etc. only 2% depend on quality and brand of the glucose meter, in this case all of them are special order from customer . All of the importers get the supplies from the manufacturers and all of the wholesalers get the supplies in our case the glucose meter from the importers. And, Regularity or sustainable supply of the glucose meters depend on the capital of the importers and currency exchange system of banks.

Based on the capital of the importer company and currency exchange system from the twelve glucose meter importers only one of them that is 8.33% import glucose meters 4 times in a year, it is the company or importer that import Sensocard glucose meter. And 7 of them that is 58.33% import glucose meter twice a year and the last four of them 33.33% import glucose meter once a year. The glucose meter impoters put this irregularity of equipment flow from manufacturer to the user because of low capital or some other reasons. The twelve imported glucose meters out of them 41.66% (5) have expense of greater than five hundred birr and their test strips are expensive than that of the 58% glucose meter.

From the twelve glucose meters imported, the Indian made glucose meters are cheaper in average but, sensocard glucose meter is the cheapest both in the glucose meter and test strip which is manufactured by the Hungarian company ; and the UK made glucose meters are the most expensive ones.

In this study, the minimum and maximum glucose concentration measured by SensoCard glucose meter and reference glucose oxidase methods were 70 mg/dl and 512 mg/dl and, 62.4 mg/dl and 556.3 mg/ dl, respectively. The mean capillary blood glucose value measured by SensoCard glucose meter was 236.74 ± 92.6 mg/dl and the mean serum glucose value measured by reference glucose oxidase method was 242.96 ± 102.4 mg/dl and. There was no statistically significant difference between the means of SensoCard glucose meter and reference glucose oxidase method glucose value (p-value=0.082). Like our study in another Study conducted in Gonder at 2014, the reference glucose oxidase method and the glucose meter showed a good correlation of 0.975 in determining blood glucose concentrations. In addition, there was no statistically significant difference between the means of blood glucose values between the two methods (9). On contaray in study Conducted in South Africa at 2012, the reference glucose oxidase method and the glucose meter showed a poor correlation of 0.575 in determining blood glucose concentrations (33).

The mean difference (bias) between the two methods was 6.22 and the strength of association (correlation coefficient) between the two methods was 0.862.The mean bias was not associated with gender, and age (p-value=0.318, 0.486 and 0.252, respectively). However, the mean bias showed statistically significant association with both reference glucose oxidase method and SensoCard glucose values (p-value <0.003 and 0.014, respectively).

The bias between the two methods increases as the concentration of glucose increases. Compared to the reference glucose oxidase method, the SensoCard glucose meter has over estimated and under estimated glucose concentrations in lower and higher concentrations of glucose, respectively. This may be due to the accuracy problem of the SensoCard glucose meter method to determine the lower and especially the higher glucose concentrations.

This study showed that, 33.33 % and 89.4% of the SensoCard glucose measurement results fall within ±15 mg/dl and ±20% of the results of the reference glucose oxidase method at glucose concentrations <75 mg/dl and ≥75 mg/dl, respectively.

In addition, 60% and 65% of the SensoCard glucose measurement results fall within ±15 mg/ dl and ±15% of the results of the reference glucose oxidase method at glucose concentrations <100 mg/dl and ≥100 mg/dl, respectively.

However, according to ISO 15197 criteria ≥95% the SensoCard glucose measurement results should fall within within ±15 mg/ dl and ±15% of the results of the reference glucose oxidasemethod at glucose concentrations <100 mg/dl and ≥100 mg/dl glucose value intervals [33,34]. Therefore, SensoCard glucose meter did not fulfill the minimum accuracy requirements of ISO 15197.

In spite of our SensoCard result, a study done in Komfo Anokye teaching hospital, Kumasi fulfilled the ISO 15197 criteria. In this study, 97% and 99% of the SensoCard glucose measurement results fall within ±15 mg/dl and ±20% of the results of the reference glucose oxidase method at glucose concentrations <75 mg/dl ≥75 mg/dl, respectively [35]. In another study done in south Africa 2012, 93% and 97% of the glucose meter measurement results fall within ±15 mg/dl and ±20% of the results of the reference glucose oxidase method at glucose concentrations <75 mg/dl ≥75 mg/dl, respectively [33].

Like our sensocard result,in a study conducted here in Gonder,TheSensoCard glucose meter and the reference glucose oxidase methods showed a good correlation of 0.975 in determining blood glucose concentrations**.** But SensoCard glucose meter underestimate blood glucose value averagely by 3.59 from reference glucose oxidase method. Moreover, the SensoCard glucose meter did not fulfill the minimum accuracy requirements of ISO 15197:2003 and ISO 15197:2013[9].

6. STRENGH AND LIMITATION OF THE STUDY

6.1 Strength

- Samples run in duplicates

6.2 Limitation of the study

- The wholesalers outside Addis Ababa were not addressed.
- The study was done only on DM patients (majorly hyperglycemic level) and it was not possible to see the accuracy of SensoCard glucose meter at lower glucose (hypoglycemic and normoglycemic) levels.
- The result was not compared with an acknowledged measure of comparison of the superior effectiveness or value.

7. CONCLUSION AND RECOMMENDATION

7.1 Conclusion

- Sensocard glucose meter is the cheapest and mostly available glucose meter in the market when compared with the nationally imported glucose meters.
- The SensoCard glucose meter and the reference glucose oxidase methods showed a good correlation of 0.862 in determining blood glucose concentrations.
- In addition, there was no statistically significant difference between the means of blood glucose values between the two methods. However, SensoCard glucose meter underestimate blood glucose value averagely by 6.22 from reference glucose oxidase method Humastar80.
- Even though SensoCard glucose meter is the cheapest and mostly available but it did not fulfill the minimum accuracy requirements of ISO 15197:2003 and ISO 15197:2013.

7.2 Recommendation

- Importers should import devices that fulfill ISO criteria.
- Further study should be undertaken including hypoglycemic and normoglycemic individuals to see the accuracy of SensoCard in low and normal levels of blood glucose in addition to high blood glucose level in diabetes mellitus patients.

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9. ANNEX

Annex- I: Operating procedures for SensoCard glucose meter

FEATURES AT A GLANCE
• Advanced biosensor technology
• Easy operation - small blood sample volume
• Optional whole blood calibration or
plasma equivalent calibration upon request
• Virtually pain-free
• Automatic turning on by detecting strip insertion
• Average test time: 5 sec.
• Strip Ejector Function
• Memory capacity: Last 500 test data
• Average calculation: 7-14-28 days
• Long life, lithium battery
• Data downloading capability to PC
• Optional human voice data telling function (Model SensoCard Plus)

• Easy code setting with code-card
• Aesthetically sleek design
030
CODE
CHECK
0.5 µl (Capillary Whole Blood)
Linearity Range
20 – 600 mg/dl (1.1 – 33.3 mmol/l)
Strip Ejector Function
Code setting with Code-cardpresent in strip box (lot specific)
Check Strip for System Checking
Measuring Time-5 Seconds
Memory 500 Test Data
With Time and Date
Human voice data telling function
(Optional-Model SensoCard Plus)

Clinical significance

The test used to know blood glucose value.

Principle

The Sensocard analysis applies the enzyme glucose oxidase and is based on advanced electrochemical technology that is specific for β-D-glucose measurement. Test strips are designed in such a way that the blood sample absorbs into the reaction area, after blood sample has been applied to the tip of test strip. In the reagent zone, glucose oxidase initiates the oxidation of glucose in blood. Intensity of produced electrons is measured by the meter and correlates well with the concentration of glucose in the blood sample. According to the manufacturer manual, the test is linear up to 33.3mmol/l (600 mg/dl). This method will accurately measure glucose levels down to 1.1 mmol/l (20 mg/dl) [9].

The Sensocard sensor is constructed on electrodes and uses GOD enzyme and ferrocenecarboxylate (Fc) mediator to carry electrons from GOD to electrode. Flavin adenine dinucleotide (FAD) is used as a coenzyme during the enzymatic reaction. The produced current

under the applied electric voltage is measured by amperometr and then converted to glucose concentration. The intensity of formed electrons is directly proportional to glucose concentration [9].

Glucose + GOD(FAD) + 2H+ Gluconolactone + GOD($FADH_2$)

GOD($FADH_2$) + 2Fc+ GOD(FAD) + 2Fc + 2 H+

Fc Fc+ + 2e- (at electrode)

Sample collection and preparation

SensoCardblood glucose test strips are designed specifically for use with fresh capillary whole blood taken from fingertip or earlobe. Venous blood, plasma, or serum samples cannot be used.

Blood testing must be performed immediately after the sample is obtained. Common anticoagulants and preservatives such as heparine and sodium EDTA are allowed to be used, but

fluoride preservatives should be avoided[9].

Equipment

- SensoCard glucose meter
- sensoCard test strip
- Lancet

Procedure

1. Insert new sensocard blood glucose test strip in sensocard blood glucose meter.
2. Apply sample (blood) on tip of the strip.
3. Read the result that displayed on the machine.
4. Eject used strip by pressing button which is located on side of the machine.

Quality control

It is recommended to run the quality control test in cases:

- When you open a new bottle of test strips
- If the meter has been dropped
- At least once per week to verify that the meter and test strips are working properly together

Results

Blood glucose test results are shown on the meter's LCD display in either mg/dl or mmol/l measurement unit. Units can be set prior the tests. The exchange rate of the units is: 1 mmol/l = 18 mg/dl. If you get an unusual test result, always check the physical circumstances being applied as follows:

1. Check if the drop of blood is completely fills the reaction zone.

2. Check if the expiration date indicated on the test strips bottle is not over yet.

3. Check if the code number of the test strip in use matches the number set in the meter.

4. Check meter ability to function properly with the „Check strip".

5. Check the system performance with CareSens Control

Limitations

- SensoCardTeststrip is designed to be used with fresh capillary whole blood samples. NEVER use serum or plasma samples.
- Hematocrit variation in sample: hematocrit between 30% to55% have no significant effect on test results. Very high (above 55%) and very low (below 30%) hematocrits may cause inaccurate test results.
- Neonates: Do not use SensoCard Test strip to test neonates. The performance of SensoCardSystem has not been validated with neonatal samples.
- Do not use fluoride as a preservative in blood samples.
- Abnormal blood specimens (i.e., high ascorbic acid, high uric acid) may effect test results. Blood glucose readings these cases should be interpreted for diagnoses with in caution.

Annex- II: operating procedure forHumastar 80(to obtain blood glucose value)

Easy Handling

>20-position reagent tray to maximize the number of tests/samples at one time

>Flexibility to run single- and two-reagent chemistries

>Open system

Unique Software Features
>Programmable washing cycles between samples
and tests minimizes carry-over
>Analysis of up to 54 samples at a time for walkaway
convenience
>Auto-rerun with pre-dilution

Accurate Measuring System

Proven technology ensures accurate measurement
and easy maintenance
>18 µl flow-cell volume for economical operation
>Auto level sensing
>High-speed movement
>Peltier-controlled flow-cell temperature
>Level sensor for wash and waste bottles
Reagent tray
Sample

Technical Data
Measuring System
> Operating mode absorbance, end-point, fixed time,
kinetic, multistandard, differential
> Throughput up to 80 tests/hour
> Light source halogen lamp 12V 20W
> Spectral range 320–690 nm
> Filter wavelengths 340, 405, 492, 505, 546, 578, 630 nm,
one free position
> Measuring range from –0.200 to 3.200 O.D.
> Flow cell 18 µl
> Incubation temperature 3 7°C ± 0.1°C
> Minimum reading volume 350 µl
> Typical reading volume 500 µl
Sample Handling
> Sample number 54 positions including samples,
calibrators and controls/tray
> Sample container cup (1.2 ml)
> Sample volume 2–200µl (1µl steps)
> Automatic dilution pre and post dilution ratio:
1:2 – 1:20

Reagent Handling
> Reagent tray 20 bottles + 1 bottle for diluent
> Reagent bottle 45 ml
> Reagent volume reagent 1 volume range:
30 to 1000 µl (1µl steps)
reagent 2 volume range:
0 to 1000 µl (1µl steps)
> Liquid detection sensor
> Reagent warming pre-heated arm
> Reagent identification position ID
> Tray exchange possible with reagent bottles

Reaction
> Number of wells 144 wells (12 wells x 12 strips)
> Well volume 1 ml
> Well temperature 3 7°C; ± 2°C
Diluter
> Syringe 1000 µl, 1 µl steps
> Accuracy ± 1 % at 5 µl
Software
> Operating system required Microsoft Windows XP or 2000®
General
> Power Supply AC115–230 V 50– 60 Hz
> Dimensions 720 (W) x 680 (D) x 530 (H) mm
> Weight 55 kg

Principle

These analyzers work by first mixing the patient sample with a reagent in a test tube or cuvette (a miniature test tube made for a particular machine) to obtain a "product" or a new substance. The amount of product produced is proportional to the amount of unknown analyte(glucose) plus reagent. A (patient sample/analyte) + R (reagent) = P (product).The product is then mixed with a chemical which causes the sample to change color.
Product +chemical = color change.
The darker the product the more analyte(glucose) is present. A light is then projected through the sample tube. The amount of light penetrating through the sample is measured electronically; light is a form of energy and can be recorded electronically. The less the light that penetrates the solution, the higher the concentration glucose.
The light projected through the sample has to be a specific wavelength for glucose. The machine usesdifferent colored filters to change the wavelength of light.

Glucose level will determine by an enzymatic colorimetric glucose oxidase method. The basic principle is that, Glucose is oxidized by glucose oxidase (GOD) enzyme to produce gluconate and hydrogen peroxide (H_2O_2). The H_2O_2 is then oxidatively coupled with 4 amino-antipyrene (4-AAP) and phenol in the presence of peroxidase (POD) enzyme to yield a red quinoeimine dye that is measured at 500 and546 nm with a colorimetric (Humastar clinical Chemistry analyzer).

The absorbance at 500 and 546 is proportional to concentration of glucose in the sample. The method has linearity from 0.0126 mmol/l (0.23 mg/dl) to 27.5 mmol/l (500 mg/dl).

Glucose +2H $_2$O + O $_2$ GOD Gluconate + H $_2$O$_2$

2H $_2$O $_2$ + 4-AAP+ Phenol POD Quinoeimine Dye + 4H $_2$O

Absorbance of the colored solution is directly proportional to the glucose concentration when measured at (500 and546) nm [10].

Equipment

- Micropipette
- Cuvette
- Test tube

Reagents

- Human glucose liquicolor.
- AutocalLyophilized multi-parameter calibrator based on human serum for clinical chemistry.
- HumaTrol NLyophilised bovine serum, target values mainly in the normal range, assayed.
- HumaTrol PLyophilised bovine serum, target values mainly in the abnormal range, assayed.

Procedure

- After separation of Serum from whole blood put reagents, samples and controls on their proper position on tray.
- Then by using personal computer which belongs to the machine with software to perform tasks ; we order the instrument to determine blood glucose value of the sample we offer.

Annex III Questionnaire used to choose glucose meter

Questionnaire for drug and medical supply importers or venders.

Company name ----------

1. What type of glucometer your company import or vender?

2. Do you have a special reason?

3. Which type of glucose meter ordered or requested by customers mostly?

4. How do you get the supplies?

5. How do you distribute to the users or customers?

6. How do you ensure the sustainability of the supplies?

7. How much it cost for single glucometer?

8. How much it cost for a pack of strips?

9. After a glucometer ordered in how much time do you submit to the customer?

Annex-IV Information sheet

Title of the project- Comparing SensoCard glucose meter with reference HumaStar 80 clinical chemistry analyzer.

Name of principal investigator- Rediet Debesom

Name of organization- Addis Ababa University,College of medicine and health science, School of medical Laboratory Sciences.

Purpose – to asses the accuracy of SensoCard glucose meter by using clinical chemistry analyzer HumaStar80 as a reference.

Procedure

- Blood sample will be collected from cubital vein (4ml) and finger capillary one drop.
- Sample will be analyzed for blood glucose value.

Risks and discomforts

During sample collection we will follow Standard operational procedures. The blood drawing may cause minor pain, at the place where blood is taken. However, this pain will disappear in few hours

Benefits

There is no direct financial benefit you get by participating in this study but the test result will be delivered timely and appropriate intervention will be pointed.

Confidentiality

Any information obtained during this study will be kept confidential. This is assured by avoiding use of any identifier and information will be recorded with code number.

Voluntary participation

Participation on this study is voluntary and you have the right to refuse participation at any time. Your decision will not result in any penalty or loss of benefits to which you are entitled. Your decision will not put at risk any present or future medical care or other benefits to which you otherwise entitled. You may ask questions now and in the future if you do not understand something that is being done. Here are addresses of individuals who you can contact

Rediet Debesom Cell phone no- 0912102406 Email address – xtina560@gmail.com

Mistire Wolde Cell phone no-091169710 Email address- mistire08@gmail.com

TedlaMindaye Cell phone no-0911634324 Email address-

Annex V- Consent Form

Participant Code Number_____

Participant full name _____

I understood the aim of the above mentioned research because informed fully in my own language and am willing to participate in the study to asses the accuracy of SensoCard glucose meter. I have been informed that medical history, blood samples will be taken and there will be minimal risk during sample collection. In addition I have been told all the information collected throughout the research process will be kept confidential. The aims of the study and possible risks were explained to me as well.

I am also informed that all the information contained within the questionnaire is to be kept confidential. Moreover I have been well informed of my right to keep hold of information, decline to cooperate and make withdrawal from the study.

It is therefore with full understanding of the situation that I gave the informed consent voluntarily to the researcher to use my blood sample for the investigation. In addition, I have had the opportunity to ask questions about it and received clarification to my satisfaction. I have also been informed that the benefit of participation is to get the results of analysis from my sample measured for free via the counselor nurse.

Unique ID No._____ Signature _____ Date_____

Interviewer's name _____Signature_____

Date of interview_____Time started_____Time finished_____

Supervisor's Name_____ Signature_____

I thank you for your cooperation

Please direct any questions or problems you may encounter during this study to:

Rediet Debesom; Department of Medical Laboratory Sciences - Addis Ababa University. Mobile 0912102406, xtina560@gmail.com.

For additional information, please contact Addis Ababa University Medical Faculty Institutional Review Board (IRB) office at:

Tel: +251-11-896 1396

Fax 251-11-5-51-1-51-30-99,

POBox9086, Addis Ababa, Ethiopia.

E-mail: aaumfirb@yahoo.com

Consent form in Oromifa

Codi lakk. : _____

Maqaa gutu: _____

Kayoonqo’anaarmanoliticaqasameafaankootingaaridhaanwaannaatiimamefdhaanaqo’anakaanata ’ukoonaanibsa. Ogaqo’anamidhabayexino aka qabufisenanmedicalaicitidhan aka qabamubarera.

Codi lakk. : _____

Mallato: _____

Guyya: _____

Maqaa dadhabi: _____

Mallato: _____

Guyya: _____

Consent form in amharic

ከ ላ ይ የ ተ ጻ ፈ ውን የ መረ ጃ ሀ ሳ ብ አ ን ብቤ ፣ የ ጥ ና ቱ ን አ ላ ማበ ግ ል ጽ የ ተ ረ ድ ቻ ለ ሁ ;፡ በ ዚ ህ ም መሠ ረ ት ለ ጥ ና ት ቡ ድ ኑ አ ባ ላ ት ያ ለ ምን ም ት እ ኖ በ መሉ ፈ ቃ ደ ኝ ነ ት በ ዚ ሁ ጥ ና ት በ መሳ ተ ፍ በ ደ ም ና መና ላ ይ ለ ሚደ ረ ጉ የ ላ ብራ ቶ ሪ ም ር መራ አ ገ ል ግ ሎ ት መሻ ሻ ል በ ማድ ደ ር ገ ው ጥ ረ ት ውስ ጥ የ በ ኩ ሌ ን አ ስ ተ ዋ ጾ ለ ማበ ር ከ ት መወ ሰ ኔ ን በ ፊ ር ማዮ አ ረ ጋ ግ ጣ ለ ሁ ፡ ፡

የ ተ ጠ ያ ቂ ው መ ለ ያ ቁ ጥ ር ---------- ፊ ር ማ----------ቀ ን ----------

የ መ ረ ጃ ሰ ብ ሳ ቢ ስ ም ---------- ፊ ር ማ----------ቀ ን ----------

መ ረ ጃ የ ተ ሰ በ ሰ በ ለ ት ስ ም ---------- የ ተ ጀ መ ረ በ ት ሰ ዓ ት ----------ቀ ን ----------

የ ተ ቆ ጣ ጣ ሪ ስ ም----------ፊ ር ማ----------ቀ ን ----------

ይ ህ ን ጥ ና ት በ ተ መ ለ ከ ተ ወ ይ ም ከ ዚ ህ ጥ ና ት ጋ ር በ ተ ዛ መ ደ መ ል ኩ ለ ሚ ያ ጋ ጥ መ ማ ች ግ ሮ ች ወ ይ ም ጥ ያ ቄ ካ ሎ ት በ ሚ ከ ተ ለ ው አ ድ ራ ሻ ይ ጠ ቀ ሙ ፡ ፡

ረ ድ ኤ ት ደ በ ሶ ም ሞ ባ ይ ል 0912102406፣ ኢ ሜ ል ፣ xtina560@gmail.com

ለ ተ ጨ ማ ሪ መ ረ ጃ ች የ አ ዲ ስ አ በ ባ ዩ ን ቨ ር ሲ ቲ ህ ክ ም ና ፋ ኩ ል ቲ ኢ ን ስ ቲ ትዩ ሽ ና ል ሪ ቪ ው ቦ ር ድ ይ ጠ ይ ቁ ፡ ፡

ስ .ቁ ፡ -251-11-5-53-87-34

ፋ ክ ስ ፡ -251-11-5-51-30-99

ኢ-ሜ ል ፡ aaumfirb@yahoo.com

Annex VI- demographic data

1. code no of participant_____
2. Ages _____

3. Sex:
Male ☐

Female ☐

Annex VII- Laboratory test results register

Code no of participants	Table6. Test Results		
	SensoCard		HumaStar 80
	capillary	venous	
BGV 001			
BGV 002			
BGV 003			
BGV 004			
BGV 005			
BGV 006			
BGV 007			
BGV 008			
BGV 009			
BGV 010			
BGV 011			
BGV 012			
BGV 013			
BGV 014			
BGV 015			
BGV 016			
BGV 017			
BGV 018			
BGV 019			
BGV 020			

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BGV 031			
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BGV 036			
BGV 037			
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BGV 039			
BGV 040			
BGV 041			
BGV 042			
BGV 043			
BGV 044			
BGV 045			
BGV 046			
BGV 047			
BGV 048			
BGV 049			
BGV 050			

Annex VIII- Declaration sheet

I, the undersigned, declare that this MSc thesis is my original work, has not been presented for a degree in Addis Ababa University or any other universities. I also declare that all sources of materials used for the thesis have been duly acknowledged.

Name of the candidate Rediet Debesom (BSc)

Signature_____

Place: Addis Ababa University School of Medical Laboratory Sciences, Ethiopia

Date of submission_____/_____/_____

thesis paper has been submitted with my approval as university advisor.

Name of advisor: Dr. Mistire Wolde (MSc, PhD)

Signature _____

We, the undersigned, agree to accept responsibility for the scientific ethics and technical conduct of the biomedical research and for the provision of required progress reports as conditions of your institution in effect of grant provision. Moreover, all investigators will assure to guarantee the safety and proper care of the study participants.

Principal investigator

Rediet Debesom (BSc, MSC candidate; Addis Ababa University)

Signature _____

Date_____

Advisors

1. Dr. MistireWolde (Msc, Phd)

Signature _____

Date_____