Clinical Study Report

For the Blood Glucose Monitoring System

Prepared Date：	Apr. 30 2018
Meter Model Number：	TD-4116
Strip Model Number：	TD-4302

Confidentiality Statement

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For TD-4116 Blood Glucose Monitoring System

Abstract

Objective:

The aim of the study was to assess the accuracy and reliability of blood glucose monitoring system in the clinical studies according to international standard ISO 15197: 2013(E) and EN ISO 15197: 2015 criteria and more stringent guidelines.

Methods:

The study sample was collected from 160 subjects comprised 12 patients with types 1 diabetes and 114 patients with types 2 diabetes, and 34 people with type unknown. The study sampled blood specimens via fingertip stick from participants with diabetes in multiple sites. Three reagent lots of test strips were used.

Results:

The evaluated devices meet the ISO total error criteria. For 97.1% of the fingertip blood samples, the difference between meter and laboratory measurements of glucose be 15% when the laboratory glucose value is ≥5.5mmol/L (≥100mg/dL) and 0.83mmol/L (15mg/dL) of the laboratory glucose value when the glucose concentration is <5.5mmol/L (<100mg/dL) according to both the CLSI and ISO recommendations.

Conclusion:

The studies verify currently available devices of blood glucose monitoring exceeded the minimum acceptable accuracy when compared test results with laboratory methods based on standard guideline.

1. Introduction

Diabetes is a chronic illness that requires complex and continuous medical care. According to the International Diabetes Federation (IDF) analysis the prevalence of diabetes mellitus and impaired glucose tolerance (IGT) showed 366 million people have diabetes in 2011, and estimated the number will have risen to 552 million[1]. Diabetes care is complex and requires multi factorial risk reduction strategies beyond glycemic control. Clinical evidences have shown the importance of tight blood glucose control for diabetes patients[2].

A medical device is any article including software, intended to be used by humans for the diagnosis, prevention or monitoring of a disease such as blood glucose meters [in vitro diagnostics (IVD)]. Early development of health informatics deal with the resources, devices, and methods required to optimize the acquisition, storage, retrieval, and use of information in health care.