

# IP REVIEW: BLOOD GLUCOSE METER



**A WHITE PAPER**

## INTRODUCTION

*In the process of advancements made on the technology front, one which has suffered a lot is nothing but the 'Human Health'! Today's fast life and corporate culture has taken its toll on lifestyles which now is synonym to more junk foods, lesser work-outs and physical and psychological stress.*

Thanks to such lifestyle, the healthcare industry has found infinite number of new opportunities; one of them being 'Diabetes related Healthcare'. Blood sugar level is nothing but direct indicative of actual life-style of a person. Deviation of the blood sugar level from normal range creates many adverse physiological changes in the body system. Hence, managing and keeping watch over the levels of glucose in the blood is critical in improving life-style.

Healthcare industry aptly identified this need of diabetics, as well as normal subjects, to regularly check their blood glucose levels. However, the industry so far cannot be considered as very successful in addressing this requirement, for, the state of the art Glucometers still have many issues with them when it comes to usability and accuracy while measuring the Blood glucose levels by patients/individuals themselves.

## HISTORY

Presently available devices for monitoring and measuring blood glucose level comprise an outcome of various step by step developments in the technology involved.

The journey of healthcare industry to address the need started in 1965, when Ernie Adams developed a paper strip product called Dextrostix as glucostrips. Such paper strips developed blue color by adding drop of blood to it and comparing it to a color chart gave an approximation of blood glucose concentration. Over the difficulties of Destrostix, Anton H. Clemens developed a reflectance meter that could read reflected light. The name of the first meter was A.R.M., the Ames Reflectance Meter [Patent No. 3604815 issued on Sep 14, 1971]. Though the concept of this light meter was based on Destrostix, it completely replaced the Dextrostix.

On the basis of the A.R.M. Technology, suddenly the Japanese researchers developed an instrument called Eytone. The original A.R.M. was heavy, bulky, and very expensive [\$495] and was designed for commercial use rather than personal utility. The Eytone, introduced in 1972, was smaller, more lightweight, easier to operate, and less expensive [\$300]. The A.R.M. was battery operated, and had all kinds of problems associated with it. This was yet another shift in the technology from A.R.M. to Eytone.





## MAJOR BREAKTHROUGH

During '70s, Ames was the global player responsible for manufacturing and selling of A.R.M. as well as Eytone. In the meantime, Boehringer, the German company, developed a competing blood glucose strip. It was called Chemstrip bG. This Chemstrip bG was followed by Accu-Chek series from Boehringer. One of them was superior to the Ames products. Till date Accu-Chek series continues to enjoy the major market share by regularly upgrading the technology through continuous R&D.

## CURRENT MARKET

Studies and statistics indicate India as the second-largest population of diabetics in the world with 50 million cases and increasing. However, currently, less than 10 percent of the blood glucose monitoring market is tapped in India. This low penetration is largely due to lack of awareness among the practitioners and patients. Despite of such lower penetration, the Indian market earned revenues of US\$ 49.7 million in 2009 and is expected to grow at a CAGR of 17.4 percent in next 5 to 6 years. Increased awareness amongst the population would indeed act as catalyst to such growth.

Various Market studies for Glucose Monitoring Devices predict:

Worldwide market is expected to be more than US\$ 16 Billion by 2014

European market is expected to be more than double the USA market by 2014

Indian market is expected to be more than US\$ 100 Million by 2014

Chinese market is expected to be more than US\$ 150 Million by 2014



## MAJOR PLAYERS

There are around 65 companies worldwide dealing in Blood Glucose Monitoring devices. But the industry is dominated by a small number of players. Roche Diagnostics and LifeScan together control approximately 65% of the global glucose meter market. Roche's Accu-Check Compact Plus and LifeScan One Touch Ultra are currently most famous and leading brands in the blood glucose monitoring industry.

Bayer and Abbott Laboratories are smaller, but significant players in this market. Some viz. All Medicus Co. Ltd., Arkray USA, Inc., Diabetes Care, Bionime Corp., Braun Melsungen AG, DexCom Inc., Hainice Medical Inc., Nipro Diagnostics, Inc., Nova Biomedical, Sanwa Kagaku Kenkyusho Co., Ltd., Sanofi-aventis, and Terumo Europe NV are slowly making their presence felt through regular innovation and R&D.

## PATENT STATISTICS

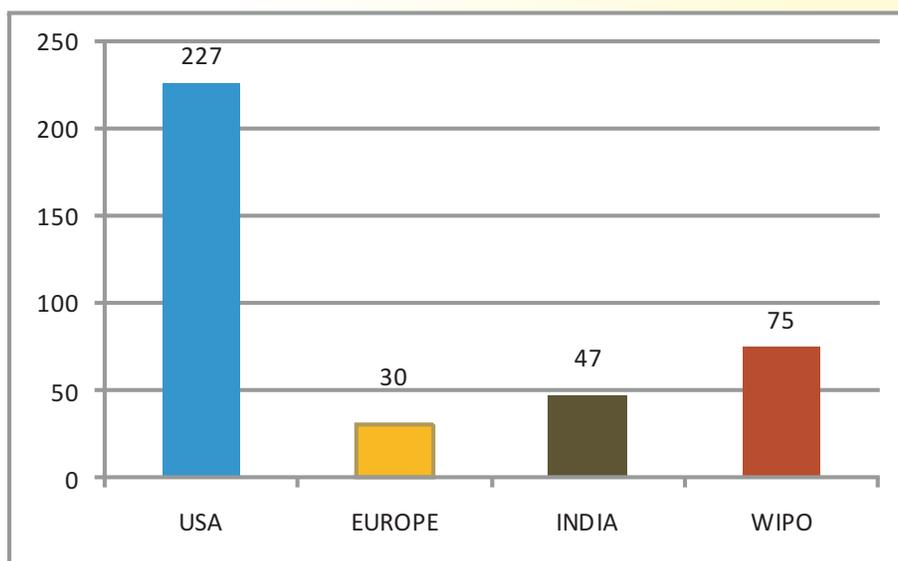
Ernest C. Adams was the first who invented Dextrostix in the early 1960s [Dextrostix Patent No. 3,092,465], and who was then employed by Ames R&D.

Tom Clemens, the inventor of the first blood glucose meter, started working on it in 1966. He built several prototypes for field trials in 1968, and filed a patent application in April, 1968. The patent, number 3,604,815, was issued to him on September 14, 1971, about two years after its launch.

The Ames Reflectance Meter quickly led to the Eyetone, made by Kyoto Daiichi Kagaku Company in Japan but marketed by Ames. The third meter, also made by Koyoto Daiichi and sold by Ames, was called the Ames Glucometer.



At present, more than 400 patent applications have been filed in the advancement of traditional Glucometer. The following graph is a current statistics of patent applications for blood glucose meter filed in some of the authorities:



Analysis of patenting trends indicate that many brands available in the market are launched with proper technology protection. For instance, Accu-Chek device alone is protected by US Patent Nos. 4,891,319; 4,924,879; 4,963,814; 4,999,582; 4,999,632; 5,053,199; 36,268; 5,206,147; 5,240,860; 5,318,584, and 35,803 and more than 17 brand names viz. Accu-chek Active, Accu-chek Advantage, Accu-chek Aviva, Accu-chek Performa, Accu-chek Compact, Accu-chek Compact Plus, Accu-chek Nano, Accu-chek Mobile etc.

A continuous effort of R&D is bringing a revolutionize diabetes care system. The Real Time Glucose Monitoring System is the new niche area in this series.



## FUTURE PROSPECTS

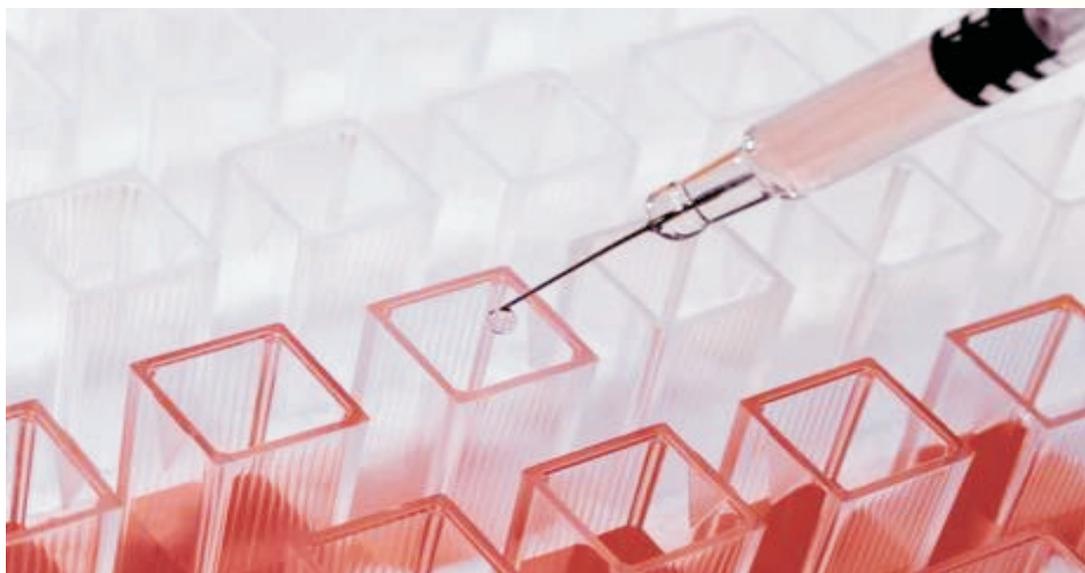
Considering the worldwide market potential, the future prospects for blood glucose monitoring device are promising. There are still many shortcomings in the current devices like:

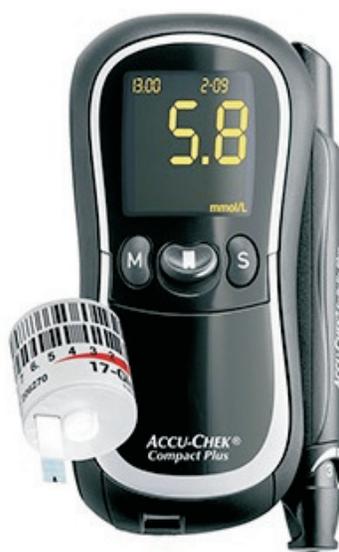
- Failure to store glucose strips properly;
- Failure to set glucose meter codes to match strip codes;
- Failure to apply sufficient blood on the meter's strip;
- Failure to use control solutions;
- Use of date-expired control solutions;
- Use of date-expired strips; and
- Failure to wash hands properly.

An ideal glucose meter should be accurate, easy to use, small, and convenient. Meters that do not require coding, are rapid and accurate, and require a very small amount of blood are preferred.

Such requirements are further opportunities available with the healthcare industry to reap upon for sustaining their presence and growth in the market.

Overcoming these issues through new innovations would certainly invade the major market sector and would help new comers to survive against the strong competitive market forces.





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