**Subject:** Reviewed ‘Limits of Acceptance’ revised as per ISO 15197:2013, and applicability of the same as per instructions of the DCG (I), dated 09.05.18

<table>
<thead>
<tr>
<th>EARLIER</th>
<th>Specifications</th>
<th>Reference</th>
</tr>
</thead>
<tbody>
<tr>
<td>Criteria for acceptance</td>
<td>95% of the individual Glucometer results shall fall within +15mg/dL of the results of the ‘Reference Method’ at glucose concentrations &lt;75mg/dL and within +20% at glucose concentrations &gt;75mg/dL. Maximum allowable deviation should be less than 15%</td>
<td>System Accuracy requirement: ISO15197:2003</td>
</tr>
<tr>
<td>REVISED (EFFECTIVE 18.10.19)</td>
<td>Specifications</td>
<td>Reference</td>
</tr>
<tr>
<td>Criteria for acceptance</td>
<td>System Accuracy requirement: 95% of the individual Glucometer results shall fall within ±15mg/dL of the results of the ‘Reference Method’ at glucose concentrations &lt;100mg/dL and within ±15% at glucose concentrations &gt;100mg/dL. Maximum allowable deviation should be less than 15%</td>
<td>ISO15197:2013</td>
</tr>
</tbody>
</table>

WHO: Laboratory Diagnosis and Monitoring of Diabetes Mellitus, 2002
Central Drugs Standard Control Organisation
Directorate General of Health Services
Ministry of Health & Family Welfare

F.No. 29/Misc/4/2016-DC (88)

To,

1. The Director,
   National Institute of Biologicals,
   Plot no. A-32, Sector-62,
   Institutional Area, Noida-201307
2. The Director General,
   Medical Technology Association of India,
   B-17, Infocity, Sector-34, Gurgaon-122001

Subject: Applicability of IS/ISO 15197 2013 version regarding glucometer test strips-Reg

Sir,

This has reference to the letter dated 02.04.2018 received from MTAI regarding the implementation date for the applicability of revised standard of IS/ISO 15197 2013 for glucometer test strips.

This office in its earlier letter no. 29/MISC/4/2013-DC (22) dated February 16, 2016 mentioned that the revised IS/ISO 15197:2013 will be effective after 36 months of its publication by BIS.

Further, BIS has issued final notification vide S.O. 3259 (E) dated October 19, 2016 where the date of establishment of IS/ISO 15197:2013 is October 19, 2016 is specified. As transition period of 36 months from the date of establishment of the said standard. Therefore, the effective date for the implementation of IS/ISO 15197:2013 shall be October 18, 2019.

Yours faithfully,

(Dr. S. Eswara Reddy)
Drugs Controller General (India)

Copy to:

1. IT Cell for uploading the information on CDSCO website
Minutes of meeting held under the chairmanship of DGHS on 14/10/2019 for allowing the use of old Glucometer available with the existing population requesting old strips for 3-4 years in the public interest as proposed by DADG (NCD), Dte, DGHS and Principal Consultant, DGHS, New Delhi

A meeting was held under the chairmanship of Director General of Health Services to deliberate on the issue of whether to continue the availability of glucose monitoring strips compatible with IS/ ISO 15197: 2003 version in the light of the IS/ ISO 15197: 2013, becoming mandatory from 18/10/2019.

The following experts/ representatives/ members were present and participated in the meeting:-

1. Dr. Sanjay Tyagi, Director General of Health Services, New Delhi - Chairman
2. Dr. (Prof.) Jagadish Prasad, Principal Consultant (JP), DGHS, New Delhi.
3. Dr. Pradeep Khasnobis, CMO (NFSG) (NCD), DGHS, New Delhi.
4. Dr. Sudhir Gupta, Addl. DDG (SG), DGHS, New Delhi
5. Dr. Ravindra Goswami, Professor, Dept. of Endocrinology, AIIMS, New Delhi.
6. Dr. B. C. Koner, Director, Professor in Biochemistry and Resource Faculty Medical Education Deptt., Maulana Azad Medical College, New Delhi
7. Dr. Chander Shekhar, Scientist Head, Innovation & Translational Research, ICMR, New Delhi
8. Dr. Reba Chabra, Dy. Director - Quality Control (Diagnostics), NIB, Noida
9. Ms. Ajanta Sircar, Scientist Grade II & Head - Biochemical Kits Laboratory, NIB, Noida
10. Dr. B.M. Makkar, RSSDI, New Delhi.
11. Dr. V.G. Somani, Drugs Controller General (India), along with officials from Medical device & IVD division, CDSCO (HQ), New Delhi
12. Mr. Deepak Aggrawal, BIS, New Delhi
13. Dr. Prakamya Gupta, Scientist C, ICMR, New Delhi

Chairman started the meeting by welcoming all the members and offered to give them their introduction. Thereafter, the issue was explained by the members from Directorate General of Health Services that large amount of glucometer has been purchased by patient in the recent past and also govt. has tendered for supply of glucometer to the different govt. programmes this may also include the glucometers of IS/ ISO 15197: 2003 version. Since, IS/ ISO 15197: 2013 is going to be mandatory from 18/10/2019, it may amount for unavailability or discontinuation of the glucose monitoring strips which are component of glucometers, for such glucometers of earlier version. The unavailability of strips for such already available glucometers with the patients may compel them to purchase new glucometers and cause
financial loss to them. Further, it was also clarified that due to similar reasons other courtiers like USA, Japan, Canada had allowed the continuation of earlier IS/ ISO 15197: 2003 version of glucose monitoring strips for their public even after adoption of IS/ ISO 15197: 2013.

After detailed deliberation of national, international situation and after taking comments from all including BIS and other members, committee decided that:-

1. The strips compatible with glucometer IS/ ISO 15197: 2003 which are already available with the large number of patients may be allowed to be continued till further three years i.e. upto 18/10/2022 in the public interest, so that the burden of cost of purchasing new glucometers does not fall on the patients.

2. Further, such glucometers of IS/ ISO 15197: 2003 shall not be allowed to be sold in the market from 18/10/2019 as present decision is made only for continued availability of the strips compatible with those glucometers and not for glucometer per-se.

3. The provisions for clear and easy identification of such strips is also required to be followed.

Meeting ended with the vote of thanks to the chair.
ADDENDUM

Decision of the Meeting for allowing the use of old Glucometer, held at Nirman Bhawan on 14.10.19 under the Chairmanship of the DGHS

(a) The strips compatible with Glucometer IS/ ISO 15197: 2003 may be allowed to be continued till further three years i.e. upto 18.10.22 in the public interest.

(b) Glucometer of IS/ ISO 15197: 2003 shall not be allowed to be sold in the market from 18.10.2019 as present decision is made only for continued availability of the strips compatible with those Glucometers.

(c) The Provision for clear and easy identification of such strips is also required to be followed.