

| Change Notice No. | Notification date | Implementation date |
|-------------------|-------------------|---------------------|
| CN/18/013 | December 17, 2018 | January 17, 2019 |

Subject : Updation of the specifications of MDI Diagnostic Products

Scope : This change notification will affect the following diagnostic products

- Absorbent Pad - All types
- Sample Pad - All types

Background:

In our efforts to provide updated information to the user/customer regarding the products that they are using, certain changes have been made in the specification based on the historical product data review in **mdi** products as mentioned above.

Need for Change:

mdi is manufacturing above mentioned product types for several years. Based on the trend analysis of data of these product types for the past few years, need to update the specifications for different test parameters was observed. Accordingly, the changes (as mentioned below) have been made in the product related literature. No change has been done in any materials of construction or manufacturing process or testing method.

How Does It Affect the User:

From a practical point of view, the changes done are upgradations in the existing system. The changes done are as mentioned below:

- Absorbent Pad

| Parameters | Old Specification | | | | New Specification | | | |
|--|-------------------|-----------|----------|-----------|-------------------|---------|----------|-----------|
| | AP045 | AP080 | AP110 | AP120 | AP045 | AP080 | AP110 | AP120 |
| Thickness (µm) | 280-480 | 730-1030 | 950-1250 | 1350-1800 | 330-570 | 650-950 | 970-1330 | 1120-1580 |
| Tare Weight (mg/cm ²) | 8.5-15.5 | 17.5-32.5 | 64-96 | 70-95 | 7-13 | 10-22 | 57-93 | 60-100 |
| Average Water Holding Capacity (mg/cm ²) | 37-47 | 60-100 | 90-150 | 130-195 | 30-50 | 52-112 | 87-147 | 110-200 |

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- Sample Pad

| Parameters | Old Specification | | | New Specification | | |
|---|-------------------|-----------------|-----------------|-------------------|-----------------|-----------------|
| | GFB-R4 (0.35) | GFB-R4 (0.6) | GFB-R7 (0.6) | GFB-R4 (0.35) | GFB-R4 (0.6) | GFB-R7 (0.6) |
| Thickness (µm) | 310-430 | 520-680 | 520-680 | 300-400 | 490-730 | 490-730 |
| Tare Weight (mg/cm ²) | 4-7 | 7-11 | 7-11 | 4-7 | 6-12 | 6.-12 |
| H ₂ O Wicking Rate, 4cm distance (sec) | 35-75 | 35-75 | 40-80 | 30-70 | 30-70 | 35-75 |

These changes have no affect on the performance of the product but it can affect the fitment of the strips in the device. The customer may validate the same at their end by checking the fitment of strip in their device.

Despite, these changes we will still honour the agreed upon specification with specific customers as per their technical profile where applicable, by offering them batches that fall within agreed upon specifications.

The accompanying product literature e.g. Certificate of Quality, Datasheets etc. will reflect the said changes.

Implementation of Change:

mdi Diagnostic products with types as mentioned above, released after the **January 17, 2019** will have the said changes in product related literature.

In case you have any queries, please feel free to contact our Technical Support Team at info@mdimembrane.com or diagnostic@mdimembrane.com.



Quality Assurance

Advanced Microdevices Pvt. Ltd.