

Measurement Accuracy Requirements for Dialysis Meters used in the Calibration of Dialysis Machines

What kind of measuring equipment is appropriate for the calibration of dialysis machines?

Very few manufacturers of dialysis machines give recommendations for the use of specific measuring equipment. Our research has found only the following recommendations shown in hemodialysis machine documentation:

B. Braun	IBP HDM99
Gambro	MESA 90DX

In order to make such a recommendation the manufacturers making the recommendation must first carry out a risk analysis. A risk analysis must be carried out by the end user in cases when the dialysis machine operators use dialysis meters for calibration that are not recommended by the machine manufacturer. Have you done this for your facility?

The most important question in a risk analysis is: **What measuring accuracy is required in measuring equipment for the calibration of dialysis machines?**

In the Guidance Section of the international standard ISO 10012-1 "General Quality Assurance Requirements for Measuring Equipment" is shown detailed information on the subject:

"The error attributable to calibration should be as small as possible. In most areas of measurement, it should be **no more than one third** and preferably one tenth of the permissible error of the confirmed equipment when in use."

This is an internationally applicable standard. This means that the measuring equipment for the maintenance of dialysis units must have a measuring accuracy which is **at least three times higher** than the measuring accuracy of the dialysis machine.

In some European countries this rule is explicitly part of the Medical Device Regulation.

Are your present meters in compliance with these critical quality standards?

The next table shows the accuracy of the conductivity and temperature measurements of popular dialysis machines.

Measuring Accuracy of Dialysis Machines

Manufacturer	Machine	Conductivity	Temperature
B. Braun	Dialog	±0.2 mS/cm	+0.5/-1.5°C
FMC	4008S	±0.1 mS/cm	±0.5°C
Gambro	AK100/200	±0.1 mS/cm	+0.5/-1.5°C
Hospal	Integra	±0.2 mS/cm	±0.5°C
Nikkisho	DBB-03	±0.1 mS/cm BC ±0.2 mS/cm GS	±0.8°C

Legend
GS = General (total) conductivity
BC = Bicarbonate conductivity

Measuring Accuracy of Meters

The following dialysis meters are included in the next chart:

IBP Medical	HDM97 and HDM99
MESA	90DX™ also valid for the Gambro Meter
MESA	NEO-2™, also valid for meters from Automata

The displayed accuracy measurements apply to 14 mS/cm. The values printed in red lie outside the minimal needed accuracy according to ISO 10012-1 (MAAI) . These values are calculated as:

MAAI (Minimum accuracy according to ISO 10012-1) = Measuring Accuracy Dialysis Machine / 3

Accuracy Dialysis Machine	MAAI	Accuracy HDM97+HDM99	MESA 90DX™	MESA NEO-2™
Conductivity ±0.2 mS/cm	±0.07 mS/cm	±0.03 mS/cm	±0.1 mS/cm	±0.05 mS/cm
Conductivity ±0.1 mS/cm	±0.033 mS/cm	±0.03 mS/cm	±0.1 mS/cm	±0.05 mS/cm
Temperature ±0.5°C	±0.17°C	±0.07°C	±0.2°C	±0.2°C

Chart of Dialysis Machines and Meters

		IBP Meters	Mesa 90DX™	Mesa NEO-2™
B. Braun	Dialog	✓	✗	✗
FMC	4008S	✓	✗	✗
Gambro	AK100/200	✓	✗	✗
Hospal	Integra	✓	✗	✗
Nikkisho	DBB-03	✓	✗	✗

- ✓ Accuracy of conductivity and temperature of the meter is higher than MAAI Suitable in accordance with the guidelines of ISO 10012-1
- ✗ Accuracy of conductivity or temperature of the meter is below MAAI . Not suitable in accordance with the guidelines of ISO 10012-1

Conclusion

Why take a risk? Use only meters which are suitable in accordance with the guidelines of ISO 10012-1. The high quality meters from IBP may be used with any type of dialysis machine.