

Potential Risk	Control Process and Risk Mitigation Strategies
Untrained operator	Software operator ID lockout
Operator error workaround QC lockout; performing patient testing in QC mode	Device distinguishes QC samples, preventing patient testing in QC mode.
Inadvertent change of units from mg/dL to mmol/l	Software administrative functions prevent operator changing.
Incorrect patient identification	Meters use ADT Location Confirmation ID and bar-coded patient wristbands; displays DOB. Operator confirms name and DOB. Meter will flag results and send a warning if patient not assigned to location where meter is used.
Fingerstick procedure	Gloves worn by testing personnel, changed between patients. Only auto-disabling, single-use lancets utilized. ATP monitoring to determine effectiveness of meter disinfection.

Table 2. Risk assessment for operator training and performance.