

ekko™ Acoustic Cell Processing System

All you need to know about the system's qualification strategy

This test matrix stems from our risk analysis and summarizes the results taken into account to implement our qualification strategy. However, it is recommended that you conduct your own process risk analysis to ensure perfect alignment.

Test matrix

Our internal tests are called Release Tests (RT) and are part of our qualification process. We recommend performing a Site Acceptance Test (SAT). Reports are issued as part of the system's documentation.

The Preventative Maintenance (PM) services are provided twice a year, one at 6-months and the other at 1-year. The PM Reports are issued as part of the system's documentation.



Tests	Test objectives	Qualification Stage		Maintenance		Software
		RT	SAT	PM - 6 month	PM - 1 year	Upgrade
SYSTEM DOCUMENTATION	Check the documentation turnover package	NA	100%	100%	100%	100%
SYSTEM CONFIGURATION	Check the software configuration of the system	100%	100%	100%	100%	100%
VISUAL INSPECTION	Check the quality finish and cleanliness of the system	100%	100%	100%	100%	100%
NAMING PLATE	Check the system naming plate	100%	NA	NA	NA	NA
FLUID HANDLING UNIT HARDWARE FUNCTIONALITY	Ensure Fluid Handling Units are functioning properly	100%	100%	100%	100%	100%
ACOUSTIC DRIVER MODULE CALIBRATION	Calibrate the Acoustic Driver Module (ADM) from manufacturer	100%	NA	NA	NA	NA
TRANSDUCER INTEGRITY	Check that the transducer is performing as intended	100%	100%	100%	100%	100%
COMMUNICATION VERIFICATION	Check the communication between System Control Unit (SCU) and Fluid Handling Unit (FHU)	100%	100%	100%	100%	100%

Tests	Test objectives	Qualification Stage		Maintenance		Software
		RT	SAT	PM - 6 month	PM - 1 year	Upgrade
VALVES	Check the operation of automated valves	100%	100%	100%	100%	100%
FRONT PANEL TEMPERATURE SENSORS	Check the functionality and accuracy of the two Infrared (IR) temperature sensors on the FHU front panel	100%	100%	100%	100%	100%
COOLING LOOP TEMPERATURE AND FLOWRATE	Check the functionality and accuracy of the Fluid Handling Unit's cooling loop	100%	100%	100%	100%	100%
NON-INTRUSIVE AIR DETECTION	Check air detection sensor operation	100%	100%	100%	100%	100%
PUMPS	Check the pumps performance	100%	100%	100%	100%	100%
ELECTRICAL STANDARD CONFORMITY	Check that the system conforms to electrical standard	100%	NA	NA	NA	NA
CRITICAL ALARMS	Check the critical alarms operation	100%	NA	NA	NA	NA
BACKUP RESTORE (DATA)	Check the data backup and restore operations	100%	NA	NA	NA	NA
POWER FAILURE AND RESTART	Check the behavior of the system when a power failure occurs	100%	NA	NA	NA	NA
WET RUN AND AUDIT TRAIL	Check the system behavior with an automatic recipe and check report contents	100%	NA	NA	NA	NA
SERVICING	Change the preventive maintenance parts	NA	NA	100%	100%	NA

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