

TE Number: TE0084040 - Date: 09 May 2018 SAP DIR: TE0084040EQ  
 Description: MSV Leak Test System

### Purpose and Scope

This document is a guide to facilitate the review of Waters' Test Equipment designed by the Waters' Milford Test Engineering Group. All new test equipment designs require at least one design review, preferably as early in the design process as is practical. At a minimum, a design review requires the approval of a second Test Engineer, the Test Engineering Manager, and a Manufacturing Engineer (except PCBA test fixtures). Invite others as deemed appropriate. Not all sections or items may be required for all equipment designs, N/A any items deemed inappropriate or unnecessary.

### Instructions

Review each line item in each section; ✓ the box to acknowledge the item was reviewed put N/A if the line is not applicable. Enter any comments below each line item and initial at the bottom of the page. Fill out Attendees section on last page with names, titles, and signatures of all attendees, and initials of System owner.

### Safety

- ☒ No pinch points, sharp edges, stability, interlocks, etc.
- ☒ Moving parts have appropriate guards.
- ☒ High voltage or current, appropriate warnings and / interlocks.
- ☒ Fluidic / pneumatic: high pressure, warnings, relief valves, safety vessels, interlocks as appropriate.
- ☒ Appropriate containment, ventilation, and leak management, for solvent and / or fumes.
- ☒ Components that may get hot or cold labeled appropriately.
- ☒ If AC powered, chassis properly grounded.

### Comments

N/A CN 09 MAY 2018

Initials TJM

TE Number: TE0084040 - Date: 09 May 2018Description: MSV Leak Test System**Mechanical / Packaging**

- ☒ UUT easily installed / removed, properly retained, but not over constrained, and easy to work on.
- ☒ Sized appropriately, consider i.e. bench top, floor standing, mobile rack, appropriate fixture kit etc.
- ☒ Appropriate considerations for moving equipment, handles, wheels, etc.
- ☒ External wiring / routed optimally, clipped, tethered or mounted as required.
- ☒ Minimal hardware used, with common drives as possible.
- ☒ Package properly vented with fans or blowers if necessary, airflow and direction considered.
- ☒ Potential leaks considered, with management to avoid damage to equipment, UUT or surrounding area.
- ☒ Integrate storage for necessary tools into the package design.
- ☒ UUT Connections (electrical / mechanical / fluidic) routed / constrained optimally.
- ☒ Designed to limit / deter intrusion of foreign material.

**Comments**

N/A CN 09 MAY 2018

Initials TJM

TE Number: TE0084040 - Date: 09 May 2018Description: MSV Leak Test System**User Interface (Software and Hardware)**

- |     |                                                                                                        |
|-----|--------------------------------------------------------------------------------------------------------|
| ✓   | Verify proper sizing, positioning, and accessibility of all controls and indicators with UUT in place. |
| ✓   | Ensure displayed data / information is concise, intuitive and appropriate for the test.                |
| ✓   | All controls, indicators, data, and interfaces labeled (intuitively).                                  |
| ✓   | Consider diagnostics for UUT troubleshooting.                                                          |
| ✓   | Ergonomics and ease of use considered.                                                                 |
| N/A | Consider use of international symbols where appropriate.                                               |

**Comments**

N/A CN 09 MAY 2018

Initials TJM

TE Number: TE0084040 - Date: 09 May 2018Description: MSV Leak Test**Service and Sustainability**

- ☒ Consider wear components, replacement, cost, and availability as well as preventative maintenance.
- ☒ Utilize "wear out" cables / tubes where possible and appropriate.
- ☒ Components used are current and not at risk of obsolescence.
- ☒ "Standard instrumentation" used where possible (such as NI CompactDAQ, Waters' fittings etc.)
- ☒ Avoid costly calibration and / or PM if not necessary.
- ☒ Consider accessibility of wear parts and troubleshooting ("Sub panels" used where appropriate, etc.).
- ☒ Use appropriate and "standard" PC if possible, with up to date OS, and programming environment.
- ☒ Consider spare part availability, lead-time, and cost.
- ☒ Waters' components designed in where appropriate.

**Comments**

N/A CN 09MAY2018

Initials TJM

TE Number: TE0084040 - Date: 09 May 2018Description: MSV Leak Test System**Software Considerations**

- |                                     |                                                                                                                          |
|-------------------------------------|--------------------------------------------------------------------------------------------------------------------------|
| <input checked="" type="checkbox"/> | Instrument Firmware verified against material BOM.                                                                       |
| <input checked="" type="checkbox"/> | Test Time, record estimated test time: Attended: <u>6 min</u> Unattended: <u>0 min</u>                                   |
| <input checked="" type="checkbox"/> | Use (create) common / universal programs and sub-programs where possible.                                                |
| <input checked="" type="checkbox"/> | Incorporate diagnostic / self-test / PM / Calibration utilities available if appropriate.                                |
| <input checked="" type="checkbox"/> | Use text / initialization files used for all specifications / attributes of UUT by part number / operator controls etc.. |
| <input checked="" type="checkbox"/> | Tester configuration (test software revision(s), -number, COM port configuration, etc.) in text file.                    |
| <input checked="" type="checkbox"/> | Opportunities for built in tests considered and discussed with R&D / REL / NPI.                                          |
| <input checked="" type="checkbox"/> | "Installer" created to install test software and supporting files.                                                       |

**Comments**

N/A CN 09 MAY 2018

Initials TJM

TE Number: TE0084040 - Date: 09 May 2018Description: MSV Leak Test System**General Design Considerations**

- |     |                                                                                                               |
|-----|---------------------------------------------------------------------------------------------------------------|
| ✓   | Equipment design is as universal as possible to facilitate use and support at any manufacturing site.         |
| ✓   | "Universal Input" power supplies used in all components.                                                      |
| ✓   | Power inlets protected appropriately, fuse(s), circuit breaker(s), line filters etc.                          |
| N/A | Ensure that suitable electrical protections for the UUT are in place, (buffers, fuses, power conditions etc.) |
| ✓   | Ensure that suitable pressure protections for the UUT are in place if necessary, (relief valves, etc.).       |
| ✓   | Test concept reviewed with NPI, REL, R&D, opportunities for defects, tests / test techniques discussed.       |
| ✓   | Test specifications "aligned" with design specifications.                                                     |

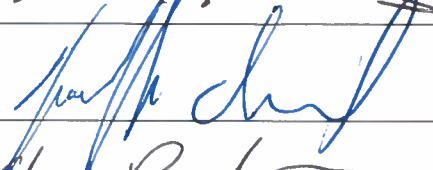
**Comments**

N/A CN 09 MAY 2018

Initials TJM

TE Number: TE0084040 - Date: 09 May 2018Description: MSV Leak Test System

## Attendees:

| Title                               | Name           | Signature                                                                            |
|-------------------------------------|----------------|--------------------------------------------------------------------------------------|
| System Owner<br>Initials <u>TJM</u> | Tyler Modelski |   |
| Test Engineer                       | Richard Davis  |   |
| Test Engineering Manager            | Gaaffar Ismail |   |
| Manufacturing Engineer              | Alex Beaudoin  |   |
| SR Test Engineer                    | Matthew Brule  |   |
| SR TEST ENGINEER                    | CHAU NGUYEN    |  |
| <del>N/A TJM 09 May 2018</del>      |                |                                                                                      |
|                                     |                |                                                                                      |