

Risk Matrix Form

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Reference	TSP WAT046538 Revision 12 (Hipot Testing)
Problem Statement	Venture Hipot GO/NO GO box verified using Chroma Tester and saw a similar low leakage current as 4.45mA (expected – 5.16mA). Therefore, it is confirmed the breaking joint of Hipot cable is creating high impedance and sinking the output voltage.

Table 1: Guidance for Severity

Level	Severity	Description	Ranking
5	Catastrophic	- Product/ Process cause fatality or potential fatality - Customer – Loss of CE marking, direct impact on registration or a recall situation - Endanger/ May Endanger operator (machine or assembly) with/ without warning	
4	Critical	- Product/ Process cause fire, injury or impairment or life-threatening injury - Worst-case audit/inspection finding (e.g., critical) - Customer – Potential loss of CE marking, potential impact of registration or potential recall - Product scrap or may have to scrap - Process cause part scrap more than 30% - Line shutdown completely or stop ship - Significant impact on product/ process quality – cause unsafe (eg: wire insulation expose and touching metal parts, parts touching critical parts (hot) – may cause smoke or fire) or facility GMP compliance	
3	Major	- Injury or impairment requiring medical treatment - Customer – No significant impact on CE marking or registration - Significant audit/inspection findings (e.g., major or multiple majors) - Potentially significant impact on product/ process quality (eg: wire insulation expose) or facility GMP compliance - Line shutdown or partial shutdown or partial stop ship - Process cause part scrap/ may have to scrap below 30% - Safety part failure	
2	Minor	- Injury or ill-health requiring first-aid only - Lowest rating audit/inspection findings (e.g: minor or multiple minors) - Minor impact on product/ process quality or facility GMP compliance	X
1	Negligible	- Not likely to cause injury - No impact on product quality or facility GMP compliance - Temporary discomfort - Cosmetic quality issues, user inconvenience - No impact or minimum impact to production line	

Table 2: Guidance for Likelihood of Re-occurrence

Level	Likelihood	Description	Ranking
5	Very high - persistent	- Certain to re-occur without intervention - Exceeded AQL three consecutive processes / deliveries - No current process control, cannot detect or is not analyzed	
4	High - Frequent	- Highly likely to re-occur without intervention - Exceeded AQL twice out of the past five processes / deliveries - Failure mode and/ or error (cause) is not easily detected by automation - Failure mode detection by operator through visual/ tactile/ audible	
3	Moderate - Occasional	- Likely to re-occur without intervention - Exceeded AQL on three or more occasions / deliveries within the past 12 months - Failure mode or error (cause) detection by operator through use of gauging or by automated controls that will detect discrepant part without notification (no prompting) - Gauging performed on setup and 1st piece check (during setup)	
2	Low - Relatively Few	- Not likely to re-occur under normal circumstances - Exceeded AQL twice occasions / deliveries within past 12 months - Failure mode detection by operator through use 100% gauging – (eg: go/no-go tool, manual torque, etc) - Failure mode detection by automated controls (automatic detection) that will detect discrepant part and notify operator (eg: light, buzzer, etc)	X

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1	Remote - Improbable	- Not expected to re-occur but potentially possible - A one-off situation - First time exceeded AQL within past 12 months - Error (cause) prevention as a result of fixture design, machine design, or part design. Discrepant parts cannot be made because item has been error-proofed by product design - Functional Failure is eliminated through preventive control - Error (cause) prevention as a result of fixture design, machine design, or part design. Discrepant parts cannot be made because item has been error-proofed by process design - Error (cause) detection by automated controls (automatic detection) that will detect error and prevent discrepant part/ process from being made	
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Table 3: Guidance for Risk Rating

Severity	Likelihood of Re-Occurrence				
	Remote - Improbable (1)	Remote - Improbable (2)	Moderate - Occasional (3)	High - Frequent (4)	Very high - persistent (5)
Catastrophic (5)	5	10	15	20	25
Critical(4)	4	8	12	16	20
Major(3)	3	6	9	12	15
Minor(2)	2	4	6	8	10
Negligible(1)	1	2	3	4	5
Low Risk		Medium Risk		High Risk	

Initial Severity: Minor

Initial Likelihood: Low – Relatively Few

Initial Risk Rating: ☒ Low

☐ Medium

☐ High

Note: In the event where **Severity** is Critical or Catastrophic or **Risk Rating** is High, action is require to mitigate the risk and/ or with Customer approval

☒ Assessment/ Comment

1) Below is the table to show the leakage current measured by using Venture and Waters GO/NO GO box on both faulty and good cable. The faulty cable is always failed and good cable is always passed. It is confirmed that Venture Hipot GO/NO GO box is able to capture the breaking joint of Hipot cable.

Equipment	Waters Load – 450K		Waters Load – 400K		Venture Load – 411K	
	Measured	Expected	Measured	Expected	Measured	Expected
Chroma Hipot Tester with faulty cable	4.15mA	4.653 ~ 4.747mA	4.68mA	5.247~5.353mA	4.45mA	5.108~5.211mA
Chroma Hipot Tester with good cable	4.69mA		5.31mA		5.16mA	

2) The DC Hipot is to verify the leakage of power supply. This is the compulsory test by power supply manufacturer prior to shipment. Venture is only performing integration, without dismantling power supply. Therefore, the power supply is always in original intact.



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☒ Mitigation

Quarantined the iBSM Plus 3U under Serial Numbers (J18BSP743G, J18BSP745G & J18BSP750G) that were built on 25-Sep-18, as well as to retest them through DC Hipot and Grounding Bonding Test.

Note: State "NA" if Not Applicable or Mitigation Not Require

☐ Attachment (if Any)

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Date & Sign: 28 Sep 2018

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