

Document VM3COP50.19 TT480 service manual Revision ID31012

Suggested Upload Document Name: **Risk Assessment For Updating Document ID31012**

Completed by [Derek Lamb](#) 02 Aug 2023

Reason for Risk Assessment

Pressure gauge part number was the for old GNW gauge, I updated it.
Added line for the Inlet 10mm 0330208 that was missing.
Minor wording changes.

Document VM3COP50.19 TT480 service manual Revision ID31012 Is linked to the Following Standards and processes



Risk Assessment Question ID31012	Does Update Affect	Risk on Update	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31012Q0 Does this Update warrant updating Any External Parties due to any Terms and Conditional Agreements E.G. Notified Body or is the update a Significate change to any ISO Certifications	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31012Q1 Viamed Ltd ISO13485:2016 Section: 7.1 Planning of product realization The organization shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. The organization shall document one or more processes for risk management in product realization. Records of risk management activities shall be maintained (see 4.2.5). In planning product realization, the organization shall determine the following, as appropriate: a) quality objectives and requirements for the product; b) the need to establish processes and documents (see 4.2.4) and to provide resources specific to the product, including infrastructure and work environment; c) required verification, validation, monitoring, measurement, inspection and test, handling, storage, distribution and traceability activities specific to the product together with the criteria for product acceptance; d) records needed to provide evidence that the realization processes and resulting product meet requirements (see 4.2.5). The output of this planning shall be documented in a form suitable for the organization's method of operations. NOTE Further information can be found in ISO 14971.	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31012Q2 Viamed Ltd ISO13485:2016 Section: 7.5.1 Control of production and service provision Production and service provision shall be planned, carried out, monitored and controlled to ensure that product conforms to specification. As appropriate, production controls shall include but are not limited to: a) documentation of procedures and methods for the control of production (see 4.2.4); b) qualification of infrastructure; c) implementation of monitoring and measurement of process parameters and product characteristics; d) availability and use of monitoring and measuring equipment; e) implementation of defined operations for labelling and packaging; f) implementation of product release, delivery and post-delivery activities. The organization shall establish and maintain a record (see 4.2.5) for each medical device or batch of medical devices that provides traceability to the extent specified in 7.5.9 and identifies the amount manufactured and amount approved for distribution. The record shall be verified and approved.	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31012Q3 Viamed Ltd ISO13485:2016 Section: 8.3.4 Rework The organization shall perform rework in accordance with documented procedures that takes into account the potential adverse effect of the rework on the product. These procedures shall undergo the same review and approval as the original procedure. After the completion of rework, product shall be verified to ensure that it meets applicable acceptance criteria and regulatory requirements. Records of rework shall be maintained (see 4.2.5).	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31012Q4 VST Ltd ISO9001:2015 Section: 8.1 Operational planning and control The organization shall plan, implement and control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by: a) determining the requirements for the products and services; b) establishing criteria for: 1) the processes; 2) the acceptance of products and services; c) determining the resources needed to achieve conformity to the product and service requirements;	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue

d) implementing control of the processes in accordance with the criteria;
e) determining, maintaining and retaining documented information to the extent necessary:
1) to have confidence that the processes have been carried out as planned;
2) to demonstrate the conformity of products and services to their requirements.
The output of this planning shall be suitable for the organizations operations.
The organization shall control planned changes and review the consequences of unintended changes,
taking action to mitigate any adverse effects, as necessary.
The organization shall ensure that outsourced processes are controlled (see 8.4).

31012Q5	<p>VST Ltd ISO9001:2015 Section: 8.5.1 Control of production and service provision The organization shall implement production and service provision under controlled conditions. Controlled conditions shall include, as applicable: a) the availability of documented information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed; 2) the results to be achieved; b) the availability and use of suitable monitoring and measuring resources; c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met; d) the use of suitable infrastructure and environment for the operation of processes; e) the appointment of competent persons, including any required qualification; f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement; g) the implementation of actions to prevent human error; h) the implementation of release, delivery and post-delivery activities</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
31012Q6	<p>Process7736 Production Start Job List When a new production is needed we the production job to the list of procedures. Check to make sure that every new job has a procedure linked to it.</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
31012Q7	<p>Process7737 Production In Production List Review the Production List, check and list those items that were started more than 30 days ago have not been through QA. Audit is carried out and production is reviewed and chased at this point.</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
31012Q8	<p>Process7738 Production Statistics Production Review, Identify any production jobs taking a long amount of time</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
31012Q9	<p>Process8000 Verification Production Paperwork Verify all production jobs have correct paperwork in the ducket with the production job</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
31012Q10	<p>ProcessProcess 5858 Opera Stock Adjustments Opera Counts bulk stock in and issues stock out against orders. Multiple processes cause stock to be used internally, Opera requires a weekly update to bring the stock count into line with whats been used outside the invoicing systems NO LONGER REQUIRED, New system live counts these now Current Known Risk Stock valuations will get inaccurate if the process is not performed. Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
31012Q11	<p>ProcessProcess 5935 Stock Allocations To allocate stock that has not automatically be linked to a repair or invoice. Current Known Risk Items that should be linked to a invoice are not in the allocations list. That items are allocated incorrectly on the list. Current Likly 2 Current Frequency 1</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>
31012Q12	<p>ProcessProcess 6838 Opera Negative Stock To find and correct opera when it reads Negative stock values. NOT REQUIRED ANYMORE Opera</p>	<p>Does Update Affect? No</p>	<p>Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required:</p>	<p>Notes On Risk / Benefits statement if required</p>	<p>Further Action Required on Issue</p>

Current Known Risk Damage Opera. Current Likly 1 Current Frequency 1		No Action Required			
31012Q13	<div><div>ProcessProcess 6850</div><div>Current Stock Levels Review current stock levels Current Known Risk If the levels are incorrect or we have a shortages then customers will not receive their goods in a timely manor. Current Likly 2 Current Frequency 1</div></div>	<div><div>Does Update Affect?</div><div>No</div></div>	<div><div>Risk Frequency due to Update</div><div>1.Improbable</div><div>Risk Likly Due to Update</div><div>2.Minor</div><div>Action Required: No Action Required</div></div>	<div><div>Notes On Risk / Benefits statement if required</div><div></div></div>	<div><div>Further Action Required on Issue</div><div></div></div>
31012Q14	<div><div>ProcessProcess 6945</div><div>Missing Stock or Adjustments To synchronise Opera stock Count against Intrastats internal movement of stock, E.G. Items that wont uniquely appear on an opera order - such as production parts. TASK IS NO LONGER REQUIRED Current Known Risk Opera and Intrastats go out of sync Current Likly 1 Current Frequency 1</div></div>	<div><div>Does Update Affect?</div><div>No</div></div>	<div><div>Risk Frequency due to Update</div><div>1.Improbable</div><div>Risk Likly Due to Update</div><div>1.Negligible</div><div>Action Required: No Action Required</div></div>	<div><div>Notes On Risk / Benefits statement if required</div><div></div></div>	<div><div>Further Action Required on Issue</div><div></div></div>
31012Q15	<div><div>ProcessProcess 6955</div><div>Production Requirements To set production job for any stock item that is needed for customer back order, warehouse requests or marketing Current Known Risk that jobs will not be added and customers orders will be delayed Current Likly 2 Current Frequency 1</div></div>	<div><div>Does Update Affect?</div><div>No</div></div>	<div><div>Risk Frequency due to Update</div><div>1.Improbable</div><div>Risk Likly Due to Update</div><div>2.Minor</div><div>Action Required: No Action Required</div></div>	<div><div>Notes On Risk / Benefits statement if required</div><div></div></div>	<div><div>Further Action Required on Issue</div><div></div></div>
31012Q16	<div><div>ProcessProcess 7048</div><div>Control of monitoring and measuring devices Control of monitoring and measuring devices Current Known Risk that equipment will be missed Current Likly 1 Current Frequency 2</div></div>	<div><div>Does Update Affect?</div><div>No</div></div>	<div><div>Risk Frequency due to Update</div><div>2.Remote</div><div>Risk Likly Due to Update</div><div>1.Negligible</div><div>Action Required: No Action Required</div></div>	<div><div>Notes On Risk / Benefits statement if required</div><div></div></div>	<div><div>Further Action Required on Issue</div><div></div></div>
31012Q17	<div><div>ProcessProcess 7673</div><div>Check Expiry Dated Stock To check that all the stock on the selves are within their use by dates. Current Known Risk Stock being dispatched that is pasts its date. Current Likly 1 Current Frequency 2</div></div>	<div><div>Does Update Affect?</div><div>No</div></div>	<div><div>Risk Frequency due to Update</div><div>2.Remote</div><div>Risk Likly Due to Update</div><div>1.Negligible</div><div>Action Required: No Action Required</div></div>	<div><div>Notes On Risk / Benefits statement if required</div><div></div></div>	<div><div>Further Action Required on Issue</div><div></div></div>
31012Q18	<div><div>ProcessProcess 7679</div><div>Check Stock Requirements Supplier Teledyne To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered. Current Known Risk That a customer is told we have stock and then we are unable to ship. Current Likly 2 Current Frequency 1</div></div>	<div><div>Does Update Affect?</div><div>No</div></div>	<div><div>Risk Frequency due to Update</div><div>1.Improbable</div><div>Risk Likly Due to Update</div><div>2.Minor</div><div>Action Required: No Action Required</div></div>	<div><div>Notes On Risk / Benefits statement if required</div><div></div></div>	<div><div>Further Action Required on Issue</div><div></div></div>
31012Q19	<div><div>ProcessProcess 7680</div><div>Check Stock Requirements Supplier Envitec To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered. Current Known Risk That a customer is told we have stock and then we are unable to ship. Current Likly 2 Current Frequency 1</div></div>	<div><div>Does Update Affect?</div><div>No</div></div>	<div><div>Risk Frequency due to Update</div><div>1.Improbable</div><div>Risk Likly Due to Update</div><div>2.Minor</div><div>Action Required: No Action Required</div></div>	<div><div>Notes On Risk / Benefits statement if required</div><div></div></div>	<div><div>Further Action Required on Issue</div><div></div></div>
31012Q20	<div><div>ProcessProcess 7681</div><div>Check Stock Requirements Supplier Posey To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered. Current Known Risk That a customer is told we have stock and then we are unable to ship. Current Likly 2 Current Frequency 1</div></div>	<div><div>Does Update Affect?</div><div>No</div></div>	<div><div>Risk Frequency due to Update</div><div>1.Improbable</div><div>Risk Likly Due to Update</div><div>2.Minor</div><div>Action Required: No Action Required</div></div>	<div><div>Notes On Risk / Benefits statement if required</div><div></div></div>	<div><div>Further Action Required on Issue</div><div></div></div>
31012Q21	<div><div>ProcessProcess 7682</div><div>Check Stock Requirements Supplier Blueprint To check that we have stock in for customer proformas and orders. Or review if any stock needs to be ordered. Current Known Risk That a customer is told we have stock and then we are unable to ship. Current Likly 2 Current Frequency 1</div></div>	<div><div>Does Update Affect?</div><div>No</div></div>	<div><div>Risk Frequency due to Update</div><div>1.Improbable</div><div>Risk Likly Due to Update</div><div>2.Minor</div><div>Action Required: No Action Required</div></div>	<div><div>Notes On Risk / Benefits statement if required</div><div></div></div>	<div><div>Further Action Required on Issue</div><div></div></div>
31012Q22	<div><div>ProcessProcess 7689</div><div>Move Stock From QA Shelf To Stock Shelf Monday Move Stock From QA Shelf To Stock Shelf Current Known Risk That stock is not replaced so it will take longer to pick goods for orders. Current Likly 2 Current Frequency 1</div></div>	<div><div>Does Update Affect?</div><div>No</div></div>	<div><div>Risk Frequency due to Update</div><div>1.Improbable</div><div>Risk Likly Due to Update</div><div>2.Minor</div><div>Action Required: No Action Required</div></div>	<div><div>Notes On Risk / Benefits statement if required</div><div></div></div>	<div><div>Further Action Required on Issue</div><div></div></div>
31012Q23	<div><div>ProcessProcess 7694</div><div>Move Stock From QA Shelf To Stock Shelf Tuesday Move Stock From QA Shelf To Stock Shelf Current Known Risk That stock is not replaced so it will take longer to pick goods for orders. The stock is not on the correct shelf. Current Likly 2 Current Frequency 1</div></div>	<div><div>Does Update Affect?</div><div>No</div></div>	<div><div>Risk Frequency due to Update</div><div>1.Improbable</div><div>Risk Likly Due to Update</div><div>2.Minor</div><div>Action Required:</div></div>	<div><div>Notes On Risk / Benefits statement if required</div><div></div></div>	<div><div>Further Action Required on Issue</div><div></div></div>

No Action Required

31012Q24	 ProcessProcess 7695 Top Up Quick Shipping Shelves Move Stock From QA Shelf To Quick Shipping Shelves Current Known Risk That stock is not replaced so it will take longer to pick goods for orders. Current Likly 1 Current Frequency 1	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31012Q25	 ProcessProcess 7736 Production Start Job List When a new production is needed we the production job to the list of procedures. Check to make sure that every new job has a procedure linked to it. Current Known Risk That a job will be carried out without a procedure. Current Likly 2 Current Frequency 2	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31012Q26	 ProcessProcess 7737 Production In Production List Review the Production List, check and list those items that were started more than 30 days ago have not been through QA. Audit is carried out and production is reviewed and chased at this point. Current Known Risk Production jobs is finished but not been QA, may get lost in the system Current Likly 2 Current Frequency 2	Does Update Affect? No	Risk Frequency due to Update 2.Remote Risk Likly Due to Update 2.Minor Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31012Q27	Does Tom Thumb Technical file #16 Of type 1 require any Notificaions and/or Risk assesment updates due to this update	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31012Q28	Does Generic CE File Attached to All Technical file #2 Of type 5 require any Notificaions and/or Risk assesment updates due to this update	Does Update Affect? No	Risk Frequency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible Action Required: No Action Required	Notes On Risk / Benefits statement if required	Further Action Required on Issue
31012Q29	Final Notes No ISO Procedures or Process are negativly affected by updating this document with the new document proposed				

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