Document VOP 06 Measurement Control Viamed VST, Calibration, QA Stock Revision ID53615

| Suggested U Completed Reason for | | | | | |
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| See Issue BSI NON C | | | | | |
| | VOP 06 Measurement Control Viamed VST, Calibration, QA Stock Revision ID53615 | | to the Following Stand | dards and processes | |
| Risk Assesment ID53615 | Question | Does Update Affect | Risk on Update | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q0 | Conditional Agreements E.G. Notified Body or is the update a Significate change to Up | Does Update Affect? | Update to Update | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| | | No V | Risk Likly Due to Update 1.Negligible Action Required: No Action Required | | 6 |
| 53615Q1 | Viamed Ltd ISO13485:2016 Section: 6.3 Infrastructure The organization shall document the requirements for the infrastructure needed to | Does Update Affect? | Risk Freqency due to Update 1.Improbable > | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| | achieve conformity to product requirements, prevent product mix-up and ensure orderly handling of product. Infrastructure includes, as appropriate: a) buildings, workspace and associated utilities; b) process equipment (both hardware and software); c) supporting services (such as transport, communication, or information systems). The organization shall document requirements for the maintenance activities. | | | | |
| | C) supporting services (such as trainsport, comminication, or miorination systems). The organization shall document requirements for the maintenance activities, including the interval of performing the maintenance activities, when such maintenance activities, or lack thereof, can affect product quality. As appropriate, the requirements shall apply to equipment used in production, the control of the work environment and monitoring and measurement. Records of such maintenance shall be maintained | | | | |
| 53615Q2 | Verification of purchased product The organization shall establish and implement the inspection or other activities | Does Update | Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible No Action Required: | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| | | Affect? | | | |
| | purchased product. When the organization becomes aware of any changes to the purchased product, the organization shall determine whether these changes affect the product realization process or the medical device. When the organization or its customer intends to perform verification at the supplier's premises, the organization shall state the intended verification activities and method of product release in the purchasing information. Records of the verification shall be maintained (see 4.2.5). | I | | | |
| 53615Q3 | 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); | Does Update Affect? No 🗸 | Risk Freqency 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 |
| | 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. | | | | |
| 53615Q4 | Control of monitoring and measuring equipment | ng and measuring equipment All determine the monitoring and measurement to be undertaken all determine the monitoring and measurement to be undertaken all determine the monitoring and measurement to be undertaken all determine the monitoring and update to U Affect? No Action all document procedures to ensure that monitoring and update to U Affect? No Action all document procedures to ensure that monitoring and update to U Affect? No Action all document procedures to ensure that monitoring and update to U Affect? No Action all determine the monitoring and update to U Affect? No Action all determine the monitoring and update to U Affect? No Action all determine the monitoring and update to U Affect? No Action all determine the monitoring and update to U Affect? No Action all determine the monitoring and update to U Affect? No Action all determine the monitoring and update to U Affect? No Action all determine the monitoring and update to U Affect? No Action all determine the monitoring and update the U Affect? No Action all determine the monitoring and update the U Affect? No Action all determine the monitoring and update the U Affect? No Action all determine the monitoring and update the U Affect? No Action all determine the monitoring and update the U Affect? No Action all determine the Matter all determine the U Affect? No Action all determine the Matter all determine the U Affect? No Action all determine the U Affect | Risk Freqency due to Update 1.Improbable > | Notes On Risk / Benefits statement if required | Issue |
| | and the monitoring and measuring equipment needed to provide evidence of conformity of product to determined requirements. The organization shall document procedures to ensure that monitoring and measurement can be | | 1.Improbable No risk, additional sticke Risk Likly Due to Update 1.Negligible Action Required: No Action Required | | z. |
| | carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements. As necessary to ensure valid results, measuring equipment shall: a) be calibrated or verified, or both, at specified intervals, or prior to use, against | | | | |

measurement

be recorded (see

standards traceable to international or national measurement standards: when no such standards

exist, the basis used for calibration or verification shall be recorded (see 4.2.5); b) be adjusted or re-adjusted as necessary: such adjustments or re-adjustments shall

4.2.5);

c) have identification in order to determine its calibration status;

d) be safeguarded from adjustments that would invalidate the measurement result; e) be protected from damage and deterioration during handling, maintenance and

storage The organization shall perform calibration or verification in accordance with

documented procedure In addition, the organization shall assess and record the validity of the previous

measuring results

when the equipment is found not to conform to requirements. The organization shall take appropriate

action in regard to the equipment and any product affected

Records of the results of calibration and verification shall be maintained (see 4.2.5). The organization shall document procedures for the validation of the application of

computer software used for the monitoring and measurement of requirements. Such software applications shall be

validated prior to initial use and, as appropriate, after changes to such software or its

application.

The specific approach and activities associated with software validation and revalidation shall be

proportionate to the risk associated with the use of the software including the effect on the ability of

the product to conform to specifications.

Records of the results and conclusion of validation and necessary actions from the

| | validation shall be maintained (see 4.2.4 and 4.2.5). NOTE Further information can be found in ISO 10012. | | | | |
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| 53615Q5 | VST Ltd ISO9001:2015 Section: 7.1.3 Infrastructure The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. NOTE Infrastructure can include: a) buildings and associated utilities; b) equipment, including hardware and software; c) transportation resources; d) information and communication technology. | Does Update Affect? No 🗸 | Risk Freqency 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 |
| 53615Q6 | VST Ltd ISO9001:2015 Section: 7.1.5.1 General 7.1.5.1 General The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements. The organization shall ensure that the resources provided: a) are suitable for the specific type of monitoring and measurement activities being undertaken; b) are maintained to ensure their continuing fitness for their purpose. The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources. | Does Update Affect? No 🕶 | Risk Freqency 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 |
| 53615Q7 | VST Ltd ISO9001:2015 Section: 7.1.5.2 Measurement traceability When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be: a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards | No 🗸 | Risk Freqency 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 |

exist, the basis used for calibration or verification shall be retained as documented information;

b) identified in order to determine their status;

c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration

status and subsequent measurement results

The organization shall determine if the validity of previous measurement results has been adversely

affected when measuring equipment is found to be unfit for its intended purpose, and

appropriate action as necessary

VST Ltd ISO9001:2015 Section: 8.5.1 Control of production and service provision The organization shall implement production and service provision under controlled

Controlled conditions shall include, as applicable:
a) the availability of documented information that defines:

 $\stackrel{\frown}{1}$ the characteristics of the products to be produced, the services to be provided, or the activities

to be performed;

conditions.

53615Q8

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

| Risk Freqency due to Update | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
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| 1.Negligible 🗸 | | |
| Action Required: | | |
| No Action Required | | |

Update

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monitoring or measurement g) the implementation of actions to prevent human error; h) the implementation of release, delivery and post-delivery activities 53615Q9 VST Ltd ISO9001:2015 Section: 8.7.1 Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on Update to Update required Issue The organization shall ensure that outputs that do not conform to their requirements Affect? 1.Improbable > Risk Likly Due to No 🗸 identified and controlled to prevent their unintended use or delivery Update The organization shall take appropriate action based on the nature of the 1.Negligible Action Required: nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming No Action Required services detected after delivery of products, during or after the provision of services. The organization shall deal with nonconforming outputs in one or more of the a) correction: b) segregation, containment, return or suspension of provision of products and services; c) informing the customer d) obtaining authorization for acceptance under concession. Conformity to the requirements shall be verified when nonconforming outputs are corrected. 53615Q10 QProcess7091 Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on Does Calibration Index Update to Update required Issue Affect? To ensure that all equipment that requires calibration is done Risk Likly Due to In the correct timescale and manor. No 🗸 Make sure all equipment has a date of calibration on it Update 1.Negligible Action Required: No Action Required 53615Q11 QProcess7998 Does Risk Frequency due Notes On Risk / Benefits statement if Further Action Required on Update to Update Verification Calibrated Equipment required 3.Occasional ➤ Risk Likly Due to Verify Equipment used is logged and up to date in the ISO calibration Index and that Affect? they have a date of calibration sticker on it. No ✔ Update 1.Negligible Action Required: No Action Required 53615Q12 \(\text{Process8044} \) Risk Fregency due Notes On Risk / Benefits statement if Does Further Action Required on required Update to Update Issue PAT Test Carry out global PAT testing Affect? 1.Improbable No 🗸 Risk Likly Due to Update 1.Negligible Action Required: No Action Required 53615Q13 OProcessProcess 6855 Risk Fregency due Notes On Risk / Benefits statement if Further Action Required on Does Update to Update required Risk Assessment HSE 1.Improbable > Risk Likly Due to Update the Site HSE file. Ensure staff are aware of this and the location of HSE Affect? equipment No 🕶 Current Known Risk Issues not done in terms. Update Current Likly 1 Current Frequency 1 1.Negligible Action Required: No Action Required 53615Q14 QProcessProcess 6856 Risk Fregency due Notes On Risk / Benefits statement if Does Further Action Required on Update to Update required Issue Fire Alarms To ensure the fire alarms, MPC (manual call points), fire extinguishers and Affect? 3 Occasional > Risk Likly Due to Update Tested by Keybury (alarms and emergency lights) annually and Airedale Fire 1.Negligible Action Required: protection (Fire extinguishers) annually. Evacuation Drills to check staff readiness No Action Required Current Known Risk If these checks are not carried out correctly and we have a fire then we are less prepared and this puts staff at risk. Current Likly 1 Current Frequency 3 53615Q15 ProcessProcess 54 Risk Freqency due Notes On Risk / Benefits statement if Further Action Required on Does Gents Toilets Update to Update Bleech the Gents Toilets Affect? 1.Improbable > Risk Likly Due to No 🗸 Process no longer required no urinal Update Current Known Risk job not carried out 3.Serious Action Required: No Action Required Current Likly 3 Current Frequency 1 Further Action Required on 53615Q16 ProcessProcess 5907 Risk Freqency due Notes On Risk / Benefits statement if Does Hoover Warehouse Update to Update required Cleaning of floors. Tidying so as to clean more effectively. Affect? 1.Improbable > Current Known Risk Dirty and unhygienic work space. Inadequate supply of Risk Likly Due to No 🗸 cleaning products Update Current Likly 1 Current Frequency 1 1.Negligible Action Required: No Action Required Does Risk Frequency due Notes On Risk / Benefits statement if Further Action Required on Sweep Warehouse Update to Update required Cleaning of floors. Tidying so as to clean more effectively. Affect? 1.Improbable > Current Known Risk Dirty and unhygienic work space. Inadequate supply of Risk Likly Due to No 🗸 cleaning products. Current Likly 1 Current Frequency 1 Update 1.Negligible Action Required: No Action Required Risk Freqency due 53615Q18 ProcessProcess 5909 Notes On Risk / Benefits statement if Further Action Required on

Update

to Update

required

Empty Warehouse Bins

| | Current Known Risk That a general Maintenance requirement may been missed. Current Likly 2 Current Frequency 1 | Affect? | Risk Likly Due to Update 2.Minor Action Required: No Action Required | | <u></u> |
|----------|--|-----------------------------------|---|--|----------------------------------|
| 53615Q30 | OxProcessProcess 7742 Boiler Check Get the gas Boilers and Hive thermostat Serviced and the Heating Checked before Winter. Current Known Risk that the heating will not work or that the boiler is not safe to use. Current Likly 1 Current Frequency 2 | Does Update Affect? | Risk Freqency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q31 | QprocessProcess 7756 Carbon Monoxide Alarm Check Carbon Monoxide Alarm is working Current Known Risk alarm does not work and kills staff Current Likly 2 Current Frequency 1 | Does Update Affect? | Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q32 | OProcessProcess 7820 North Yorkshire Council Waste Tranfer The renewal of our waste transfer agreement with North Yorkshire County Couoncil Current Known Risk That we cannot get rid of waste or we have a supplier that takes waste but does not dispose of it in the correct legal manor. Current Likly 1 Current Frequency 2 | | Risk Freqency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q33 | OprocessProcess 7821 Controlled Waste Description And Transfer The renewal of our waste transfer agreement with our waste disposal companies Current Known Risk That we cannot get rid of waste or we have a supplier that takes waste but does not dispose of it in the correct legal manor. Current Likly 1 Current Frequency 2 | Does Update Affect? | Risk Freqency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q34 | © ProcessProcess 7835 Electrics Need Checking To get the Electrics checked by External Electriction, so certificate can be provided for Employee Safety Current Known Risk Not carried out in a timely manner Current Likly 1 Current Frequency 1 | Does Update Affect? | Risk Freqency 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 |
| 53615Q35 | © Process Process 7836 Central Heating For Winter Reset the Heating for Winter Current Known Risk Building too hot / cold Current Likly 1 Current Frequency 1 | Does Update Affect? No 🗸 | Risk Freqency 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 |
| 53615Q36 | QProcessProcess 7713 Review Roles And Responsibilitys Ensure All tasks allocated to active Members of staff, Current Known Risk That not all jobs will be allocated to a member of staff. That we may not share out jobs in a appropriate way. Risk of being over faced. Current Likly 2 Current Frequency 2 | Does Update Affect? | Risk Freqency 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 |
| 53615Q37 | QProcessProcess 7845 7.1.4 Environment Of Operations Determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. Merged into 7729 can close the tasks Current Known Risk no risk. to the process, however risk maybe some problems may be brought up that are better left un-brough up, which may result in loss of staff while dealing with a problem that is suddenly brought to light that was better not addressed. Current Likly 1 Current Frequency 1 | Does Update Affect? No 🗸 | Risk Freqency 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 |
| 53615Q38 | ^Q ProcessProcess 45 Main Server Status Check the status of the Main Server Current Known Risk If the Main server fills up it can stop all processes completely. Replacing the server requires technical knowledge of Linux, LAMP set up, and Samba settings | Does Update Affect? | Risk Freqency due to Update 3.Occasional Risk Likly Due to Update 3.Serious Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| | Current Likly 3 Current Frequency 3 | | | | |
| 53615Q39 | ^Q ProcessProcess 52 Software Verification Clear Down Backup Emails Keeps a month or so backup emails Current Known Risk Mail box gets full and bounces emails back Current Likly 2 Current Frequency 1 | Does Update Affect? | Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required: | Notes On Risk / Benefits statement if required | Further Action Required on Issue |

| 2/11/202 | 24, 13:18 vmserver10.thevault.me.uk/intranet/da Current Known Risk Stock gets mislaid in the warehouse Current Likly 2 Current Frequency 1 | Affect? | Risk Likly Due to Update 2.Minor Action Required: No Action Required | | =1&A=&vui=2&use |
|----------|---|-----------------------------------|--|--|----------------------------------|
| 53615Q51 | ^Q -ProcessProcess 7858 Software Validation Attempt To QA Some Stock Test the QA System that Staff not trained for QA are unable to QA a Product. Current Known Risk Untrained staff QA/Processing Product Current Likly 1 Current Frequency 3 | Does Update Affect? No 🗸 | Risk Freqency due to Update 3.0ccasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required: | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q52 | ^Q -ProcessProcess 7861 Software Validation Of Training Documents Forced Reading Software Validating Of Training Documents via Forced Required Reading Current Known Risk required reading not read. Current Likly 1 Current Frequency 2 | Does Update Affect? No 🗸 | Risk Freqency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required: | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q53 | © Process Process 7091 Calibration Index To ensure that all equipment that requires calibration is done. In the correct timescale and manor. Make sure all equipment has a date of calibration on it Current Known Risk That equipment we use to may not be calibrated when we need it. Or the date may not be attached. Current Likly 1 Current Frequency 2 | Does Update Affect? No 🗸 | Risk Freqency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q54 | Question of the Company of the Co | Does Update Affect? No V | Risk Freqency due to Update 2.Remote Pisk Likly Due to Update 1.Negligible Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q55 | %ProcessProcess 7746 UPS Invoices VST Go on to the UPS web site and download the unpaid invoices. Working from the accounts package to find the date that these need to go back to. These are then entered on to the accounts package and paid. Current Known Risk That invoices are missed or a payment is not made. The accoun is put on stop. Current Likly 1 Current Frequency 2 | Does Update Affect? No 🗸 | Risk Freqency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q56 | New Process Process 7747 UPS Invoices Vandagraph Go on to the UPS web site and download the unpaid invoices. Working from the accounts package to find the date that these need to go back to. These are then entered on to the accounts package and paid. Current Known Risk That invoices are missed or a payment is not made. The accoun is put on stop. Current Likly 1 Current Frequency 2 | Does Update Affect? No t | Risk Freqency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required: | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q57 | Q-ProcessProcess 5940 Thumb Nail Processor Generate the Thumbs nails for the document Index Current Known Risk No real risk as pocuments with out a thumbail do not break the system, simply show a generic thumbnail required icon. Current Likly 2 Current Frequency 1 | Does Update Affect? | Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required: | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q58 | ©ProcessProcess 7739 Intrastats Amendment Log Intrastat Changes updates. Logging system to enable roll back should anything break Current Known Risk None, The updates are automatically logged and stored for easy retrieval. This process is simply to add notes to new updates Current Likly 2 Current Frequency 1 | Does Update Affect? | Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required: | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q59 | © Process Process 7126 Intrastats Requested Page updates Fix general errors in intrastats such as Spelling errors or columns not lining up Current Known Risk that a fix is missed or a page does not work Current Likly 2 Current Frequency 1 | Does Update Affect? | Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q60 | QProcessProcess 5905 Price Checking Check we have consistent pricing across the different databases. | Does Update Affect? | to Update 1.Improbable Risk Likly Due to Update | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| | Current Known Risk Incorrect pricing can cause customer confusion | | 3.Serious Action Required: | | 1 |

| 53615Q61 | © ProcessProcess 5866 UPS Shipping Fuel Surcharge UPS surcharges change on a monthly basis. The internal system requires updating so the postage rates can be calculated by anyone correctly. *PROCESS REPLACED WITH WORLDSHIP Current Known Risk We pay more for shipping than we charge to the customer Current Likly 1 Current Frequency 2 | Does Update Affect? No 🕶 | Risk Freqency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
|----------|--|-----------------------------------|--|--|----------------------------------|
| 53615Q62 | QProcessProcess 6972 UPS Shipping Fuel Surcharge task no longer required, WE switched toups online WITH LIVE PRICES Update the UPS rates to ensure we charge the correct amount of carriage Current Known Risk Computer/network breakdown Current Likly 1 Current Frequency 2 | Does Update Affect? No 🕶 | Risk Freqency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q63 | © ProcessProcess 7711 Import Bank CSV Download the most recent bank statement from the bank website Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 1 | Does Update Affect? No • | Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q64 | QProcessProcess 7706 Update Virus Software And Scan For Viruses Updating of anti-virus software and scanning computers for viruses Current Known Risk Computer/network breakdown Current Likly 2 Current Frequency 2 | Does Update Affect? No 🗸 | Risk Freqency 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 |
| 53615Q65 | © ProcessProcess 46 Backup Server Status Check the status of the Backup Server, is done at same time as primary server Current Known Risk Replacing the server requires technical knowledge of Linux, LAMP set up, and Samba settings, Current Likly 1 Current Frequency 3 | Does Update Affect? | Risk Freqency due to Update 3.Occasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q66 | ^Q ProcessProcess 44 Secure Socket Level Certificate Encrypt data sent back and forth to Intrastats so it can be used off site Current Known Risk If certificate fails you can bypass the warnings and continue and still have encryption. only risk would be a man in the middle attack, however as Intrastats is in constant use warnings would be given to all members of staff as it trys to update. risk is minimum Current Likly 1 Current Frequency 1 | Does Update Affect? No 🕶 | Risk Freqency 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 |
| 53615Q67 | ©ProcessProcess 49 Wifi Ensure Viamed Wifi is operational Current Known Risk Lose remote internet connection Loss of access to phone system on mobile devices Current Likly 1 Current Frequency 1 | Does Update Affect? | Risk Freqency 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 |
| 53615Q68 | © Process Process 50 Guest Access Wifi Backup Internet Connection Current Known Risk Wifi might go down Current Likly 3 Current Frequency 1 | Does Update Affect? | Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 3.Serious Action Required: No Action Required: | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q69 | © ProcessProcess 7832 Cleardown Emailed Invoices Backup of all Sent Emails sent to External Address for Verification Current Known Risk that we may loose some emails Current Likly 1 Current Frequency 1 | Does Update Affect? | Risk Freqency 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 |
| 53615Q70 | © ProcessProcess 7823 Saftey Tester Data Backup the Fluke ESA615 Safety tester CE Copy any files to the Z Drive - safety tester backupdata Current Known Risk That this will not be carried out. Current Likly 1 Current Frequency 1 | Does Update Affect? | Risk Freqency 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 |
| 53615Q71 | © Process Process 7698 Clean Toilets Cleaning of surfaces, equipment, floors. Tidying so as to clean more effectively. Current Known Risk Dirty and unhygienic bathrooms. Inadequate supply of cleaning | Does Update Affect? | Risk Freqency due to Update 1.Improbable Risk Likly Due to | Notes On Risk / Benefits statement if required | Further Action Required on Issue |

Risk Likly Due to

Emailing of Invoices to customers

Current Likly 2 Current Frequency 1

2.Minor

Action Required:

| | | | No Action Required | | |
|-----------|--|-----------------------------------|---|--|----------------------------------|
| 53615Q93 | QProcessProcess 7679 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 | Does Update Affect? No 🕶 | Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q94 | Q-ProcessProcess 7826 Goods In Processes To Receive Goods from Suppliers Current Known Risk incorrectly booked in not booked in Current Likly 2 Current Frequency 2 | Does Update Affect? | Risk Freqency 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 |
| 53615Q95 | CProcessProcess 7752 SRS Folder Ensure all outstanding repairs are being dealt with Current Known Risk repairs get stuck in the system Current Likly 2 Current Frequency 1 | Does Update Affect? No 🕶 | Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q96 | QProcessProcess 7749 Check Repair Quotes Check the quotes that we send out for the repairs we have received in. Current Known Risk That mistakes may be missed. That details will be incorrect and it will affect the customer. Current Likly 2 Current Frequency 2 | Does Update Affect? No 🗸 | Risk Freqency 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 |
| 53615Q97 | © Process Process 7685 Repairs Ready For Invoice Process Invoice for completed repairs. Current Known Risk repair has errors on it Current Likly 1 Current Frequency 1 | Does Update Affect? No 🗸 | Risk Freqency 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 |
| 53615Q98 | ^Q -ProcessProcess 7684 Repairs Ready For Quote Process Repairs Ready For Quote Current Known Risk If process does not get performed, we likly to loose customers, get complaints over not responding to customers returned goods Current Likly 1 Current Frequency 1 | Does Update Affect? | Risk Freqency 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 |
| 53615Q99 | Q.ProcessProcess 7674 Check Repairs Ready For Invoice List Review the repairs ready For invoice List in intrastats. Current Known Risk That repairs will be missed. Current Likly 2 Current Frequency 1 | Does Update Affect? | Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q100 | Q-ProcessProcess 7671 Humanmed Non Conformances Humanmed Non Conformances Current Known Risk non conformations not logged. Current Likly 2 Current Frequency 2 | Does Update Affect? No 🗸 | Risk Freqency 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 |
| 53615Q101 | Q-ProcessProcess 7870 Software Validation Non Conformance Product Risk Feedback Loop Scope to check the automatic system of tagging product non conformance and other issues to the post market surveillance review report. Current Known Risk issues not carried out Current Likly 1 Current Frequency 1 | Does Update Affect? No 🗸 | Risk Freqency 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 |
| 53615Q102 | Q-ProcessProcess 7869 Hand Drill Checklist This is a check list to ensure safe use of the Hand Drill Current Known Risk That injury will occur Current Likly 1 Current Frequency 3 | Does Update Affect? No 🕶 | Risk Freqency due to Update 3.Occasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q103 | QProcessProcess 7868 Pillar Drill Checklist This is a check list to ensure safe use of the Pillar Drill | Does Update Affect? | Risk Frequency due to Update 3.Occasional Risk Likly Due to | Notes On Risk / Benefits statement if required | Further Action Required on Issue |

Current Likly 2 Current Frequency 1

| 53615Q114 QProcessProcess 6945 | | | | |
|--|-----------------------------------|--|--|----------------------------------|
| 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 | Does Update Affect? | Risk Freqency 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 |
| 53615Q115 AProcessProcess 6955 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 | Does Update Affect? | Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 2.Minor Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q116 AprocessProcess 5853 Vacuuming Of The Office, Hall And Meeting Room Ensure customer facing areas are vacuumed Current Known Risk Vacuum malfunction Current Likly 1 Current Frequency 1 | Does Update Affect? | Risk Freqency 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 |
| 53615Q117 **OprocessProcess 5878 Empty Office Bins Emptying of the recycling and waste bins into external bin for refuge collectors Current Known Risk Waste is not removed or waste is not correctly placed in bins Current Likly 1 Current Frequency 1 | Does Update Affect? | Risk Freqency 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 |
| 53615Q118 QProcessProcess 5906 Empty Paper Bins Emptying of the recycling and waste bins into external bin for refuge collectors Current Known Risk Waste is not removed or waste is not correctly placed in bins Current Likly 1 Current Frequency 1 | Does Update Affect? No 🕶 | Risk Freqency 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 |
| Clean Duckets Cleaning of duckets Current Known Risk Writing that is still left on the ducket mean that the new information may not be clear. Current Likly 1 Current Frequency 1 | Does Update Affect? No • | Risk Freqency 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 |
| S3615Q120 QProcessProcess 7961 R D Room - Tidy, Empty Bins, Remove Cups. Caution Around Oxygen Supply To Clean Tidy the research and development rooms Current Known Risk staff absent so job is not carried out job not carried out well Current Likly 1 Current Frequency 1 | Does Update Affect? | 1 2 | | Further Action Required on Issue |
| 53615Q121 QProcessProcess 7896 Tree In Car Park To Maintain the Tree in the Car Park Current Known Risk the tree may become unsafe Current Likly 1 Current Frequency 3 | Does Update Affect? No 🕶 | Risk Freqency due to Update 3.Occasional Risk Likly Due to Update 1.Negligible Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q122 ProcessProcess 8030 Purchase Order Invoice Review Confirm the Price on our purchase order matches the price charged by the supplier Current Known Risk We over pay for products or services Current Likly 1 Current Frequency 2 | Does Update Affect? | Risk Freqency due to Update 2.Remote Risk Likly Due to Update 1.Negligible Action Required: No Action Required | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q123 Does Generic CE File Attached to All Technical file #2 Of type 5 require any Notificaions and/or Risk assesment updates due to this updat | Does te Update Affect? | Risk Freqency due to Update 1.Improbable Risk Likly Due to Update 1.Negligible | Notes On Risk / Benefits statement if required | Further Action Required on Issue |
| 53615Q124 Final Notes | | Action Required: No Action Required | | |

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