Incident Investigation Reporting

Quarantine the Device

- Retain any accessories and/or consumables involved, as they may be required during the investigation.

Request Investigation

- As soon as possible, contact MD-Vigilance@ortus.co.uk to report the incident.
- Tell us you are requesting an investigation, and include the following details in your email:
  - Date and time of incident
  - Organisation incident reference number
  - Brief description of event, including patient outcome
  - Whether the event has been declared a Serious Incident

Request Device Uplift

- Use this form to let The Ortus Group know that you need to return your device: https://knowledge.theortusgroup.com/id-like-to-return-my-device-for-service
- Or, contact medsupport@ortus.co.uk for assistance.

Complete the Incident Investigation Form

- Look out for an email from MD-Vigilance@ortus.co.uk.This will contain an Incident Investigation Form for completion.
- **Starred (*) sections are mandatory – without this information we will be unable to continue the investigation process.**
- Please include as much additional information as possible – the more we know the more quickly we can complete the investigation and return your device to you.

Return The Form and Associated Mission Files

- Return the form to MD-Vigilance@ortus.co.uk and attach any associated mission files.
- If the mission files have not been uploaded to your server, The Ortus Group will retrieve them from the device if they are still present.
- **Without access to the mission files, we may not be able to fully investigate the incident.**

Investigation Begins

- Only when all items and documents have been received will The Ortus Group begin an investigation into the functionality of the device.
- The MedServ team will complete a technical review of the device, in conjunction with a review of the mission files.
    - Please note, in certain situations, for example when there has been an adverse event, the device may be returned to the manufacturer with the relevant mission file(s), SBARDR report and Incident Investigation Form.
- The CAS team may contact attending personnel to complete an SBARDR (Situation, Background, Assessment, Recommendation, Decision, Resolution) report.
  This is nothing to worry about, we are simply trying to get a good idea of the events that occurred – we are investigating the device, not you! For example, we may want to find out what solutions were attempted during the incident, to rule out possible causes.

- **Please note: we will not undertake an investigation without the required information as we are legally required to assess the incident, and when necessary, report it to the relevant authorities for ongoing vigilance monitoring.**
  Therefore, the mandatory fields of the Incident Investigation Form are required, as a minimum, to allow us to this.

Repair Work Completed

- If a technical fault or damage is found during the technical review, your organisation will be contacted and a plan of action agreed before any repairs are carried out.

Incident Report Generated

- An incident report will be written by The Ortus Group and/or the manufacturer. We will share this report with your organisation. The report will include details of any faults found, and if necessary, recommended actions.

Contact Information

- During the investigation process, any queries or additional information can be sent to MD-Vigilance@ortus.co.uk.
- Please include the incident reference number (and the Ortus ticket number, if known) in the subject line of any correspondence.
