	DOC No: AEU00537	TITLE: UNATTENDED PRODUCTION & INSPECTION OF CHIESI PARTS			Advanex Europe Ltd Head Office: Southwell Site Mill Park Way, Southwell Nottinghamshire, UK, NG25 0ET ☎ 00 44 (0) 1636 815555 ☎ 00 44 (0) 1636 817725 Bilborough Site ☎ 00 44 (0) 115 9293931 ☎ 00 44 (0) 115 9295773 Video Conference IP 80 176 189 113 www.advanexeurope.co.uk general@advanexeurope.co.uk
	Revision.	Date	Supersedes	Page	
	01	30/Apr/2015	N/A	1 of 4	

DOCUMENT APPROVAL

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Your signature indicates that this document has been prepared in accordance with company standards or guidelines and adequately reflects the tasks and deliverables necessary.

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Your signature indicates that, you have reviewed this document and that it accurately and completely reflects the tasks and deliverables necessary.


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Your signature indicates that this document complies with company standards or guidelines; and that the documentation and information contained herein complies with applicable regulatory, corporate, divisional/departmental requirements, and current Good Manufacturing Practices.

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	Revision.	Date	Supersedes	Page	
	01	30/Apr/2015	N/A	2 of 4	

1.0 PURPOSE

- 1.1. The purpose of the document is to define the SOP (Standard Operating Procedures) to be followed by ADVANEX EUROPE Ltd, in order to ensure that all product manufactured during unattended periods is done so in a controlled and consistent manner.

2.0 SCOPE

- 2.1. For the purpose of this SOP manufacturing only includes the forming and in-line heat treatment operations.
- 2.2. All equipment and processes on the Pharmaceutical section have been formally qualified and validated. All personnel working on the Pharmaceutical section are responsible for ensuring that no changes are made to the process without full change control as defined in SOP/PH001 (Document Number AEU00226).

3.0 TERMS, DEFINITIONS & ABBREVIATIONS

- 3.1. Unattended periods refers to times when parts are manufactured without the presence of an operative or inspector thereby preventing standard IPC requirements to be met.


4.0 HEALTH, SAFETY & ENVIRONMENTAL

- 4.1. GMP (Good Manufacturing Practice) guidelines apply (Document Number AEU00389).
- 4.2. Within the factory area safety footwear is mandatory.
- 4.3. Within the factory area Safety glasses must be worn.

5.0 ASSOCIATED DOCUMENTS

- 5.1. Machine Log: (Document Number AEU00258): Used to record any unplanned activity on a machine.
- 5.2. Quarantine List.
- 5.3. Weigh Count (Document Number AEU00542).
- 5.4. Measurement Procedure for CHIESI Flap Return Spring (Document Number AEU00540).
- 5.5. Measurement Procedure for CHIESI Yoke Spring (Document Number AEU00541).
- 5.6. Non-Conforming Product & Corrective & Preventive Action (Document Number AEU00004).
- 5.7. Production Record Sheet: For recording the quantity of parts produced and wire information.
- 5.8. Works Order Instructions: Allowing full traceability for the batch.

6.0 PROCEDURE

	DOC No: AEU00537	TITLE: UNATTENDED PRODUCTION & INSPECTION OF CHIESI PARTS			Advantex Europe Ltd Head Office: Southwell Site Mill Park Way, Southwell Nottinghamshire, UK, NG25 0ET ☎: 00 44 (0) 1636 815555 ☎: 00 44 (0) 1636 817725 Bilborough Site ☎: 00 44 (0) 115 9293931 ☎: 00 44 (0) 115 9295773 Video Conference IP 80.176.189.113 www.advantexeurope.co.uk general@advantexeurope.co.uk
	Revision.	Date	Supersedes	Page	
	01	30/Apr/2015	N/A	3 of 4	

6.1. Preparation.

- 6.1.1. **Stop the Machine.** Ensure that the forming machine is stopped and the oven is empty of any components.
- 6.1.2. **Separating Components Made During a Manned Production Run.** The machine setter must ensure that an empty collection bin is positioned at the exit of the heat treatment furnace.
- 6.1.3. **SPC Inspection.** Perform a SPC inspection of five components from the last collection bin as per CHIESI Flap Return Spring (Document Number AEU00540) or Measurement Procedure for CHIESI Yoke Spring (Document Number AEU00541), as appropriate. If components are correct, proceed to step 6.1.4, if not an investigation is performed to determine the reason for the deviation and any adjustment deemed necessary carried out and checked, any effected components are scrapped.
- 6.1.4. **Clean Machine.** Clean each coiling machine with pressurised air to ensure that it is free of parts.
- 6.1.5. **Check Correct Carousel Rotation.** The setter will ensure that the carousel is set to turn to each collection bin at the correct frequency by ensuring the correct quantity of components are in each collection bin taken from the carousel.
- 6.1.6. **Empty Carousel.** Empty all components from the Carousel for each machine that is to be left to produce during an unattended period. These are to weigh counted in accordance with SOP Weigh Count (Document Number AEU00542), ensuring that they are correctly identified.

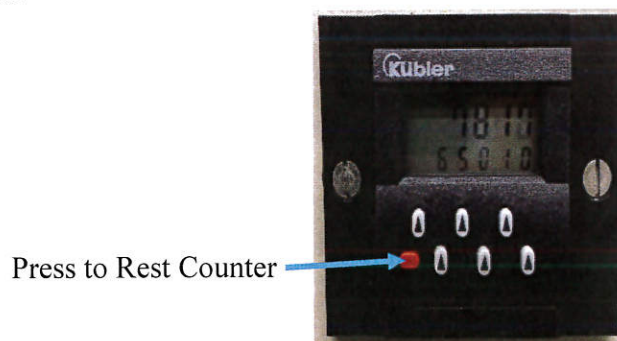



Figure 1: Counter control panel.

- 6.1.7. **Reset the Counter.** Press the Red button on the counter to reset component count, as shown in Figure 1:
 - 6.1.8. **Final Check.** The process will be checked to ensure that all trips and switches are working correctly and that the heat treatment oven is correctly set as detailed on the Works Order Instructions.
- ## 6.2. Unattended Run Completion.
- 6.2.1. **Stop the Machine.** If the forming machine was still running, ensure that it is stopped and the oven is emptied of any components.

 ADVANEX	DOC No: AEU00537	TITLE: UNATTENDED PRODUCTION & INSPECTION OF CHIESI PARTS			Advanex Europe Ltd Head Office: Southwell Site Mill Park Way, Southwell Nottinghamshire, UK, NG25 0ET ☎ 00 44 (0) 1636 815555 ☎ 00 44 (0) 1636 817725 Bilborough Site ☎ 00 44 (0) 115 9293931 ☎ 00 44 (0) 115 9295773 Video Conference IP: 80.176.189.113 www.advanexeurope.co.uk general@advanexeurope.co.uk
	Revision.	Date	Supersedes	Page	
	01	30/Apr/2015	N/A	4 of 4	

6.2.2. **Check Machine Face.** Upon the completion of a quantity of parts manufactured during an unattended period, the setter / operative will check the machine face to ensure that no distorted parts have been produced. The machine will be turned over by hand to check that the tooling is still functioning correctly.

6.2.3. **First off Inspection of the Subsequent Attended Run.** A first off inspection is performed at the commencement of the subsequent attended run. If this is acceptable, the previous parts manufactured during an unattended period are judged to be acceptable pending SPC inspection. If the inspection reveals any non-conformity, the parts are identified using a 'reject material' card and segregated pending further investigation as directed in procedure Non-Conforming Product & Corrective & Preventive Action (Document Number AEU00004). The Section Leader and Head of QA are informed. Any such product is recorded on the production records and the quarantine list as applicable.

6.2.4. **SPC Check.** Random samples of 5 parts will be taken from the collection bins in accordance with the relevant Work Order Instruction sheet and checked on all SPC dimensions and the results recorded, as per CHIESI Flap Return Spring (Document Number AEU00540) or Measurement Procedure for CHIESI Yoke Spring (Document Number AEU00541) as appropriate.

6.2.5. **If SPC is OK.** If the contents of the bins are judged to be acceptable, the bins can be emptied and the machine set to produce an attended run as detailed in step 6.3.1.

6.2.6. **If SPC is Not OK.** If any non-conforming product is found the entire contents of the bin shall be immediately scrapped and the Section Leader and Head of QA informed. Each bin on the carousel shall be identified as suspect using a 'reject material' card until the parts are checked and either found to be acceptable or reject. As a precaution the last acceptable bin will also be scrapped. Any scrapped product must be recorded on the production record.

6.3. Clean Down.

6.3.1. At the end of an unattended production run all collection bins will be fully emptied of components, weigh counted as per SOP Weigh Count (Document Number AEU00542), then cleaned with pressurised air.