pharmaxis

**FM-164-08** 

**Date Effective:** 26-Nov-21

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## EQUIPMENT BREAKDOWN AND MODIFICATION RECORD

1.	1. Equipment Details		EBM No:
Descrip	ption:	Tag/Identification N	umber:
Locatio	on:	Date of Incident:	
Record	raised in ELB-012 by:	Record raised on:	
2.	Description of breakdown / modification (Refer SOP-219	for instructions)	Attachment:
1100000			
Remov	al from service required:		Yes 🗆 / N/A 🗆
Sign:			Date:
3.	Works proposed to address breakdown/modification.		Attachment:
List in	steps, the actions proposed to address breakdown/modifi	ication:-	
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	steps, the actions proposed to address breakdown/modifi	ication:-	
List in	steps, the actions proposed to address breakdown/modifi	ication:-	Date:

Authorisation signature and date:

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Reference: SOP-219

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## EQUIPMENT BREAKDOWN AND MODIFICATION RECORD

4. Pre-Approval (as required)	EBM No:	
Name	Sign	Date
QA Delegate-		
5. Preliminary assessment to Quality due to breakd (as required)	own/modification	Performed □ Not Performed □
Potential impact to Quality: □Yes □No □Unknown at this sta	ge	Quality Document
(Provide additional information in Sec 6 for any ascertained after completion of work)		Reference if any:
Comments:-		
Approved by QA Delegate (Name):		
Sign:		Date:
6. Description of repair / modification works undertake	n 	Attachment:
		7
Quality Document Reference if any potential Quality impact ha	as been identified	
Sign:		Date:

Authorisation signature and date:



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Reference: SOP-219

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## EQUIPMENT BREAKDOWN AND MODIFICATION RECORD

7. Replacement Equipment Details (N/A	if not required)	EBM No:
Faulty Equipment	Replacement Equipment	
Tag No:	Tag No:	
Manufacturer:	Manufacturer:	
Model:	Model:	
Serial No:	Serial No:	
8. Like for Like replacement of equipment (	N/A if not required)	
Comments:		
Assessed By:		Date:
Approved By (Equipment Owner or Delegate):		Date:
Updated details on ELB-019:	Y	Yes □ / No □ / N/A □
Updated details on relevant Calibration/Maintenance Lo		Yes □ / No □ / N/A □
Implemented By:		Date:
9. Repair/Replacement/Modification Report	e and affectiveness	
checks.	A And effectiveness	Attachment:
- CHOOKS		
		<del>-</del>
Sign:		Date:
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Authorisation signature and date:

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## EQUIPMENT BREAKDOWN AND MODIFICATION RECORD

	10. Checks Following repair / replacement or modification	EBM No:
Α.	Described equipment (Section 1) fit for use?	Yes□/No□
A.	If No, deleted from Calibration/Maintenance Log(s):	Yes□/No□/ N/A□
В.	Equipment returned to Service, if removed as per Section 2?	Yes□/No□/ N/A□
	Date equipment returned to Service(N/A if not applicable)	Date:
C.	Replaced equipment released for use?	Yes□/No□/ N/A□
<b>.</b>	ELB-019 Updated with equipment details(Date released/decommissioned)?	Yes□/No□/ N/A□
D.	Faulty equipment disposed of:	Yes□/No□/ N/A□
р.	Finance notified of disposal:	Yes□/No□/ N/A□
Sign:		Date:
	11. EBM Record Closure Approval	
Approved By (Equipment Owner or Delegate):		
Approved By (QA Department): Date:		
ELB-01:	2 Updated By:	Date:

Authorisation signature and date:

DBC

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Reference: SOP-219