

# Quality Assurance Certificate

Product Release Certificate

Certificate No: 140

## Lu-mini

Model	ITL PN	Qty	Serial Number
Lu-mini	S130768	47	975-100001 - 975-100047

DMR Ref:	DMR-001
Concessions Applied:	966-007, 966-008 & 975-004

### VISUAL INSPECTION & PERFORMANCE ASSESSMENT:

Certify that the product has been visually inspected & tested in accordance with final test procedures, results verified as meeting specification and all results recorded.

Name: Amber Zolubaite

Signed:



Position: Quality Engineer

Date:

08 October 2020

### RELEASE AUTHORISATION:

This is to certify that the product(s) specified above have been manufactured and tested under the control of a quality assurance system registered with BSI to the requirements of :-

ISO 9001: Certificate No FM 20699

ISO 13485: and EN ISO 13485: Certificate No MD91401.

Name: Amber Zolubaite

Signed:  .....

Date: 08 October 2020

Approved Signatory for Integrated Technologies Ltd.

TEL: +44 (0) 1233 638383

QA@itl.co.uk

www.itl.co.uk

PROJECT No:	975	DOC No:	QA-07-975-S130891	ISSUE No:	1
PCR (ECR) No:	975-003			SHEET:	1 OF 2

**FOR TRAINED PERSONNEL ONLY  
WEAR GLOVES WHEN HANDLING UNIT**

UNIT SERIAL NUMBER:	100012	VARIANT: (E.g. Nemis, MET)	Nemis
---------------------	--------	-------------------------------	-------

1. Carry out **CP-975 TOP LEVEL ASSEMBLY COMMISSIONING PROCEDURE** and record results /information as indicated.
2. Stop test on all failures and comply with Reject Procedure.

STAGE 1 – VISUAL INSPECTION			
STEP	EXPECTED RESULT	RECORDED RESULT	PASS (✓/X)
1	Beeper sounds, Splash screen is displayed, beeper sounds again and Main Menu is displayed	OK	✓
2	Test software opens on PC	OK	✓
3	1. Shutter testing starts and the download screen is displayed on the unit. 2. The shutter in the reader opens and closes the shutter 49 times before taking a reading which is displayed in the 'Reading' box. 3. The readings are not stored and will alternate between and shutter 'closed' reading and a shutter 'open' reading. 4. Readings should be less than 100 and both 'open' and 'closed' should be similar.  SHUTTER: <input type="text" value="CLOSED (0/1031)"/>  READING: <input type="text" value="DARK: 10"/>	OK	✓
4	1. Testing stops 2. In the 'Shutter' window is a figure of e.g. 0/984. The '0' is the total number 'Faults' recorded and '984' is total number of tests performed. 3. <b>There must be <u>no</u> shutter faults recorded!</b> 4. Unit restarts	OK	✓
5	1. Protocol screen displayed 2. The unit recognises the sample vessel is inserted.	OK	✓

<b>PROJECT No:</b>	975	<b>DOC No:</b>	QA-07-975-S130891	<b>ISSUE No:</b>	1
<b>PCR (ECR) No:</b>	975-003			<b>SHEET:</b>	2 OF 2

	Countdown screen displayed followed by Test Result Screen		
6	Test screen is displayed	OK	✓
7	<ol style="list-style-type: none"> <li>Results database displays a total of 6 recorded results</li> <li><b>NOTE: Record results on QA-07</b></li> <li>Results should be within +/-50 RLU of the calibrator value</li> </ol>	S15, S48, S65, S01, S11, S28	✓
8	<ol style="list-style-type: none"> <li>Unit screen goes blank before restarting</li> <li>Window pops-up on Test software to say that the unit has been re-set.</li> </ol>	OK	✓
9	Application opens.	OK	✓
10	<ol style="list-style-type: none"> <li>Unit synchronises to app</li> <li><b>NOTE:</b> check the serial number is correct</li> <li>Download screen displayed on unit before it restarts.</li> <li>"Successfully completed" message appears on application</li> <li>Log-in Screen is now displayed on the unit with 'GUEST' user shown.</li> </ol>	OK	✓
11	<ol style="list-style-type: none"> <li>Unit will go into 'Standby mode'</li> <li>The 'standby mode screen' is displayed showing the 'wake-up' button in the bottom right corner.</li> </ol> <p><b>NOTE: The Standby button must remain visible for the 10 seconds</b></p>	OK	✓
12	Application closes and unit turns off.	OK	✓
13	N/A		
14	N/A		

**SIGN OFF – PRODUCTION**

Certify that the results recorded are true and accurate in accordance with the requirements of CP-975-S130891

<b>Name:</b>	Matthew Mills	<b>Signed:</b>	Mills
<b>Position:</b>	VITL	<b>Date:</b>	30th September 2020



## P975 NEMIS LU-MINI CONFIGURATION RECORD

PROJECT No:	975	DOC No:	QA-13-975	ISSUE No:	2
ECR No:	975/001	SHEET:	1	OF	1

HARDWARE VERSION:	V.1.00	UNIT SERIAL NUMBER:	975-100012
FIRMWARE VERSION:	V.1.00	UNIT PART NUMBER:	S130768
		MODULE TYPE	MET

Ref No	Module	Part Number	PCB Iss No	Serial Number	ML	ECR Change
1	LCD	E440058	N/A	N/A		
2	Control PCB	S128652	2	0200		
3	Reader PCB	S128669	5	0197		

**Programmable Device Record:**

Ref No	DEVICE	LOCATION	VERSION	ECR
1				
2				
3				
4				

**Record of in-process rework/adjustment**  
 Concessions 966-007, 966-008 and 975-004 applied