



UNMATCHED SERVICE  
SINCE 1979...

**TRANSASIA BIOMEDICALS LIMITED**  
**PERFORMANCE QUALIFICATION**

**TRANSASIA®**  
Bio-Medicals Ltd.

Customer Name: UJALA CYGNUS RAINBOW HOSPITAL, AGRA  
 Model: EC 90 Serial Number: 4457-2-202209

**ANNEXURE-A**

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**1. APPROVAL:**

**1.1 Prepared By:**

| Name              | Designation            | Signature         | Date |
|-------------------|------------------------|-------------------|------|
| VED PRAKASH SINGH | APPLICATION SPECIALIST | <i>Vedprakash</i> |      |

**1.2 Checked By:**

| Name | Designation | Signature | Date |
|------|-------------|-----------|------|
|      |             |           |      |
|      |             |           |      |
|      |             |           |      |

**1.3 Approved By:**

| Name | Designation | Signature | Date |
|------|-------------|-----------|------|
|      |             |           |      |



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## TRANSASIA BIOMEDICALS LIMITED

### PERFORMANCE QUALIFICATION

|  |                     |                |               |
|--|---------------------|----------------|---------------|
| Customer Name: UJALA CYGNUS RAINBOW HOSPITAL, AGRA | Model: <u>EC 90</u> | Serial Number: | 4457-2-202209 |
|--|---------------------|----------------|---------------|

**2. OBJECTIVE:**

The objective of this protocol is to establish documented evidence for the Performance Qualification of EC 90 and to ensure that the results obtained are within the pre-determined Acceptance Criteria.

**3. PRE-REQUISITES:**

Following Pre-requisites are required before the execution of Performance Qualification.

- Completion of Installation Qualification (IQ) prior to PQ.
- Completion of Operational Qualification (OQ) prior to PQ.

**4. TEST PLAN:**

Perform precision study for both Erba Norm & Erba Path controls and check the recovery (for both level QC) & CV% (for both level QC) during the Performance Qualification of EC 90.

- Follow the EC 90 Quick Start Guide for Test procedure.

**5. ACCEPTANCE CRITERIA:**

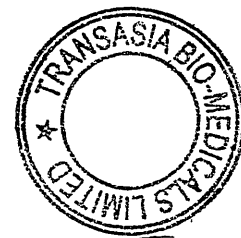
Acceptance criteria are based on the precision studies conducted by manufacturer for EC 90.

**6. SUMMARY:**

| Level                           | Norm QC | Path QC |
|---------------------------------|---------|---------|
| Lot #                           |         |         |
| Mean                            |         |         |
| SD                              |         |         |
| CV%                             |         |         |
| Range Limit Low                 |         |         |
| Range Limit High                |         |         |
| Acceptable Criteria (Max.value) |         |         |
| Status                          | PASS    | PASS    |

Traceability: Instrument Raw Data printouts.

Note: This report is effective from the date of approval.





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HOSPITAL, AGRA

Model: EC 90

Serial  
Number:

4457-2-  
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#### Annexure-B

Instrument Raw Data to be attached as printout attachments in Annexure-B.



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## TRANSASIA BIOMEDICALS LIMITED

### OPERATIONAL QUALIFICATION

Customer Name: UJALA CYGNUS RAINBOW  
HOSPITAL, AGRA

Model: EC 90

Serial  
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4457-2-  
202209

TRANSASIA®  
Bio-Medicals Ltd.

#### ANNEXURE-A

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| 5.     | Acceptance Criteria | 2         |

#### 1. APPROVAL:

##### 1.1 Prepared By:

| Name             | Designation      | Signature | Date |
|------------------|------------------|-----------|------|
| PUSHPENDRA SINGH | SERVICE ENGINEER |           |      |

##### 1.2 Checked By:

| Name | Designation | Signature | Date |
|------|-------------|-----------|------|
|      |             |           |      |
|      |             |           |      |
|      |             |           |      |

##### 1.3 Approved By:

| Name | Designation | Signature | Date |
|------|-------------|-----------|------|
|      |             |           |      |



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## TRANSASIA BIOMEDICALS LIMITED

### OPERATIONAL QUALIFICATION

|   |                     |                   |                   |  |
|---|---------------------|-------------------|-------------------|--|
| Customer Name: UJALA CYGNUS RAINBOW<br>HOSPITAL, AGRA | Model: <u>EC 90</u> | Serial<br>Number: | 4457-2-<br>202209 | <b>TRANSASIA®</b><br>Bio-Medicals Ltd. |
|   |                     |                   |                   |  |

#### 2. OBJECTIVE:

The objective of this protocol is to establish documented evidence for the Operational Qualification of EC 90

#### 3. PRE-REQUISITES:

Following Pre-requisites are required before the execution of Performance Qualification.

- Completion of Installation Qualification (IQ) prior to PQ.

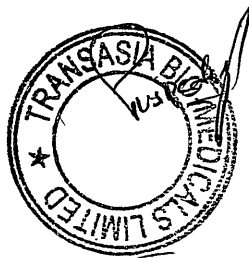
#### 4. TEST PLAN:

- Setting up the System settings by selecting date, time and language.
- Checked Tubes inserted, found OK.
- Checked EC Cartridge inserted with Biosensor found OK.

#### 5. ACCEPTANCE CRITERIA:

Prime Up and 2P Calibration are resulted with NO ERROR.

Note: This report is effective from the date of approval.





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## TRANSASIA BIOMEDICALS LIMITED

### INSTALLATION QUALIFICATION

Customer Name: UJALA CYGNUS RAINBOW  
HOSPITAL, AGRA

Model: EC 90

Serial  
Number:

4457-2-  
202209

**TRANSASIA®**  
Bio-Medicals Ltd.

#### ANNEXURE-A

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#### 1. APPROVAL:

##### 1.1 Prepared By:

| Name             | Designation      | Signature | Date |
|------------------|------------------|-----------|------|
| PUSHPENDRA SINGH | SERVICE ENGINEER |           |      |

##### 1.2 Checked By:

| Name | Designation | Signature | Date |
|------|-------------|-----------|------|
|      |             |           |      |
|      |             |           |      |
|      |             |           |      |

##### 1.3 Approved By:

| Name | Designation | Signature | Date |
|------|-------------|-----------|------|
|      |             |           |      |



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## TRANSASIA BIOMEDICALS LIMITED

### INSTALLATION QUALIFICATION

TRANSASIA®  
Bio-Medicals Ltd.

Customer Name: UJALA CYGNUS RAINBOW  
HOSPITAL, AGRA

Model: EC 90

Serial  
Number:

4457-2-  
202209

#### 2 OBJECTIVE:

The objective of this protocol is to establish documented evidence for the Installation Qualification of EC-90.

#### 3 PRE-REQUISITES:

Initial Inspection of the unit carried out and the details are as follows:

- Analyzer Condition Report:  
Found the Analyzer along with accessories to have been delivered in satisfactory condition and no external physical damaged observed.
- External Requirements for Installation:
- Input voltage of 100-240VAC 50/60Hz 60W
- Recommended Operational Conditions 15-35 °C / 15-90% Humidity
- In order to ensure the safety of the analyzer and the operator, following conditions must be guaranteed.
- The power supply system (Protection Class B & Category II) must be compatible with the voltage and current specifications indicated on the serial number plate attached to the rear of the analyzer; and it is recommended to check the efficiency of the electrical system from time to time.
- The material for the operator's safety (gloves, containers for disposing of used expendable items, surface disinfectants) must always be available.

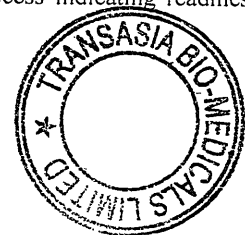
#### 4 UNPACKING AND PLACEMENT :

- The unpacking & positioning of the analyzer must comply with the instructions indicated in user manual.

#### 5 INSTALLATION :

- The installation of the analyzer must be in accordance to the instructions indicated in the EC 90\_Quick Start Guide (Available in Accessory box along with the analyzer).
- After verification of the installation of the analyzer, flip toggle the power switch to ON (I).
- Once switched on, the analyzer guides the operator to perform 11 relevant steps needed to install the analyzer.
- On confirming the final step, the analyzer performs a Start Up Completion (Prime Up followed by 2P Calibration)
- The analyzer returns to Home Screen after successful Start Up completion process indicating readiness for sample measurement.

Note: This report is effective from the date of approval.



Page 2 of 2

## Certificate of Analysis

Product name: EC 90

Serial No.: 4457-2-202209

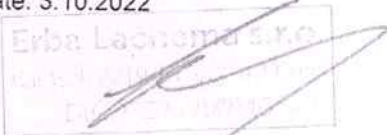
Catalog No.: INS00079

Manufacturing Date: 09/2022

### Results of testing

| Testing             | Limit/criterion        | Test results | Remarks |
|---------------------|------------------------|--------------|---------|
| Instrument QC       | pass                   | pass         | ok      |
| QC measurements     | more than 91,7 % valid | 100 %        | ok      |
| Conclusive SW check | pass                   | pass         | ok      |
| Completeness        | pass                   | pass         | ok      |

Date: 3.10.2022



Ing. R. Herrmann  
Quality Manager

COA\_EC 90\_257-2



| Plán kontrol č.<br><b>10020690</b> |                                | Vydání č.<br><b>5</b>                       | Vydal / kontakt<br>PROKESOVA |
|------------------------------------|--------------------------------|---|------------------------------|
| Číslo dílu<br><b>10020690</b>      |                                | Index změny<br><b>0</b>                     | Datum vydání<br>09.09.2022   |
| Název dílu<br><b>EC 90</b>         |                                | Datum tisku<br>27.09.2022                   |                              |
| Tvorba KP - útvár                  |                                |   |                              |
| Číslo oper.                        | Parametry                      | Specifikace<br><br>Tolerance                | Kontrolní metoda             |
|                                    |                                |   | Výsledky                     |
| 1                                  | SOP                            | 257-2                                       | ✓                            |
| 2                                  | Funkční zkouška (system check) | viz Protokol o kontrole                     | ✓                            |
| 3                                  | Etiketa přístroje              | podle korekturního vzorku<br>CC/L/210/22/A  | ✓                            |
| 4                                  | Etiketa na krabici             | podle korekturního vzoru<br>CC/L/210/22/A   | ✓                            |
| 5                                  | Uživatelský manuál             | podle korekturního vzoru<br>CC/IFU/042/22/D | ✓                            |
| 6                                  | Verze software                 |   | 1.11.3                       |
| 7                                  | Kompletnost                    | dle ZVŠ                                     | ✓                            |
| 8                                  | Záznam o výrobě šarže          |   | ✓                            |
|                                    |                                |   |                              |

## System QC protocol

### EC 90 Analyzer

|                          |               |                    |           |
|--------------------------|---------------|--------------------|-----------|
| Serial number of product | 4457-2-202209 | Manufacturing Date | 09/2022   |
| SW version               | 1.11.3        | Test performed by  | Burianová |
| EC cartridge lot         | 2111139       | Test performed at  | 29.9.2022 |

| No.                            | Performance content        | Limit/Criterion   | Sample    | Notice   | Pass/Fail |
|--------------------------------|----------------------------|---|-----------|----------|-----------|
| 1.                             | Final QC instrument        | valid protocol  | -         | -        | ✓         |
| <b>Basic QC measurements</b>   |                            |   |           |          |           |
| 2.                             | QC measurement performance | less than 8,3% of all values are out of target range      | Erba Norm | 100 %    | ✓         |
|                                |                            |   | Lot:      | 2105150B |           |
| Erba Path                      |                            |   | 100 %     | ✓        |           |
| Lot:                           |                            |   | 2203101   |          |           |
| 3.                             |                            |   |           |          |           |
| <b>Conclusive system check</b> |                            |   |           |          |           |
| 4.                             | SW check                   | all tasks could be done per SW, no SW-freeze              | -         | -        | ✓         |
| 5.                             | Mechanical check           | no mechanical damage detectable                           | -         | -        | ✓         |
| 6.                             | Put into operation         | no additional maintenance for put into operation required | -         | -        | ✓         |
| 7.                             | Closing activities         | Cleaning, visual tube check, shutdown                     | -         | -        | ✓         |

| Disposition | Name      | Date      | Signature        |
|-------------|-----------|-----------|------------------|
| Pass/Fail   | Burianová | 29.9.2022 | <i>Burianová</i> |

|                |               |
|----------------|---------------|
| Serial number: | 4457-2-202209 |
| Date:          | 29.09.2022    |
| Technician     | Burianová     |

|  |                     |
|--|---------------------|
| Materials                              | Lot Number          |
| EC cartridge plus iCa<br>Elite H Clean | 2111139<br>20210906 |

*buianova*

|           |   | QC      |       |       |        | Target values |      |      |      |
|-----------|---|---------|-------|-------|--------|---------------|------|------|------|
|           |   | Na      | K     | iCa   | Cl     | Na            | K    | iCa  | Cl   |
| Erba Norm | 1 | 121,260 | 4,028 | 0,574 | 87,990 | 121           | 3,97 | 0,53 | 88,7 |
|           | 2 | 122,310 | 4,201 | 0,586 | 88,650 | 133           | 4,36 | 0,62 | 97,7 |
|           | 3 | 121,870 | 4,080 | 0,579 | 89,670 | 156           | 6,64 | 1,11 | 130  |
|           | 4 |         |       |       |        | 192           | 7,30 | 1,29 | 142  |
|           | 5 |         |       |       |        |               |      |      |      |
|           | 6 |         |       |       |        |               |      |      |      |
|           | 7 |         |       |       |        |               |      |      |      |
|           | 8 |         |       |       |        |               |      |      |      |
|           | 9 |         |       |       |        |               |      |      |      |
| Mean      |   | 121,870 | 4,080 | 0,579 | 88,650 |               |      |      |      |

|                 |  |
|-----------------|--|
| Requirement     | 8,3% of all QC measurement can be out of the range |
| Material        | Erba Norm  |
| Values OutR     | 0  |
| Total measur. % | 12   |
| Result          | OK   |

|           |   | Na      | K     | iCa   | Cl      | Na  | K    | iCa  | Cl  |
|-----------|---|---------|-------|-------|---------|-----|------|------|-----|
| Erba Path | 1 | 170,750 | 6,565 | 1,070 | 127,750 | 174 | 6,64 | 1,11 | 130 |
|           | 2 | 170,980 | 6,719 | 1,085 | 127,060 | 192 | 7,30 | 1,29 | 142 |
|           | 3 | 171,240 | 6,522 | 1,078 | 127,640 |     |      |      |     |
|           | 4 |         |       |       |         |     |      |      |     |
|           | 5 |         |       |       |         |     |      |      |     |
|           | 6 |         |       |       |         |     |      |      |     |
|           | 7 |         |       |       |         |     |      |      |     |
|           | 8 |         |       |       |         |     |      |      |     |
|           | 9 |         |       |       |         |     |      |      |     |
| Mean      |   | 170,980 | 6,522 | 1,078 | 127,640 |     |      |      |     |

# Záznam o výrobě přístroje

(Assembly protocol)

Produkt (Product): EC 90

Podmínky testu (Test conditions): 23.2 °C 1.39 %

Katalogové číslo (Catalogue number): INS00079

Výrobní číslo (Serial number): 4457-2-202209

## Verze PCB (PCB version)

|              |     |               |     |                  |     |
|--------------|-----|---------------|-----|------------------|-----|
| PowerPcb (1) | 1.5 | HeadPcb (1)   | 1.5 | ProximityPcb (3) | 1.4 |
| CPUPcb (2)   | 1.5 | BubblePcb (3) | 1.2 | PrinterPcb (2)   | 1.2 |

## Montážní pracoviště (Workbenches)

## Závada (Issue)

## Závada (Issue)

|   |                        |   |   |                       |   |
|---|------------------------|---|---|-----------------------|---|
| Pracoviště 1 (Workbench 1)<br>(datum a podpis) (date and signature) | 27.7.2022<br>VALENTOVA | ✓ | Pracoviště 3 (Workbench 3)<br>(datum a podpis) (date and signature) | 29.9.22<br>JEDLIČKOVÁ | ✓ |
| Pracoviště 2 (Workbench 2)<br>(datum a podpis) (date and signature) | 27.9.22<br>JEDLIČKOVÁ  | ✓ | Pracoviště 4 (Workbench 4)<br>(datum a podpis) (date and signature) | 29.9.22<br>Slouka     | ✓ |

## Základní HW test (Basic HW test)

|   |                     |             |   |
|---|---------------------|-------------|---|
| Kontrola pojistky (Checking glass tube fuse)      | Přístroj (Instrum.) | 250 V 2 A T | ✓ |
| Kontrola hlavního vypínače (Checking main switch) | Přístroj (Instrum.) | 0-off; 1-on | ✓ |

## Funkční test

|  |        |  |        |
|--|--------|--|--------|
| Zapnutí+přihlášení+instalace SW (Start initial setup + install SW) | SW     | OK/ nOK                                | ✓      |
| Loader version (Boot loader version)                               | 1.02   | Version (Firmware version)             | 1.11.3 |
|  |        | Jazyková verze (Language file version) | 0.53   |
| Kontrola načtení čipu RFID na kazetě (Checking RFID module)        | SW/ HW | OK/ nOK                                | ✓      |
| Kontrola čtečky čárového kódu (Checking barcodereader)             | SW/ HW | Přihlášení (Log in)                    | ✓      |
| Kontrola konektorů USB (Checking USB-Interface)                    | SW/ HW | OK/ nOK                                | ✓      |

MAC adresa (MAC address): 2 2 - EC - 90 - 00 - 4457 (např. pro SN 3123, MAC adresa je 22-EC-90-00-31-23)  
(example for SN 3123, MAC address is 22-EC-90-00-31-23)

|  |        |         |   |
|--|--------|---------|---|
| Uložení verzí HW a SN (PCB,) (Record HW version and SN)  | SW/ HW | ~       | ✓ |
| Kontrola tiskárny (Checking printer)   | SW/ HW | OK/ nOK | ✓ |
| Kontrola LAN připojení (Checking Ethernet interface)   | SW/ HW | OK/ nOK | ✓ |
| Kontrola pumpy (Checking pump)   | SW/ HW | OK/ nOK | ✓ |
| Kontrola ventilů (Checking valves)<br>(V1, V2, V3, V4, V5)   | SW/ HW | OK/ nOK | ✓ |
| Kontrola senzoru otevření páky jehly (Checking flap sensor)  | SW/ HW | OK/ nOK | ✓ |
| Kontrola senzoru vzdálenosti u jehly (Check proximity sensor)<br>zavřená páka (closed flap) (350-500) 44.2               | SW/ HW | OK/ nOK | ✓ |
| Kontrola LED osvětlení za jehlou (Check LED at sample needle)<br>Červená, zelená, modrá, vypnuto (Red, green, blue, off) | SW/ HW | OK/ nOK | ✓ |

## Senzor bublin (Bubble sensor)

|                                      |                   |                   |
|--------------------------------------|-------------------|-------------------|
| Senzor (Sensor)                      | Rozsah (Range)    | Výsledek (Result) |
| Prázdný systém (empty)               | > 500             | 2490              |
| Vypočtená hodnota (calculated value) | <30% hodnoty výše | 747               |

## Test s ISE simulátorem (dodaný z MTEK) (Checking signal with simulator delivered from MTEK)

| Senzor (Sensor)         | Poloha 1 (záporný signál)<br>Position 1 (negative sensors signal) |      | Poloha 2 (kladný signál)<br>Position 2 (positive sensors signal) |                                |      |                      |
|-------------------------|---|------|--|--------------------------------|------|----------------------|
|                         | Rozsah hodnoty [mV]<br>(Range)                                    |      | Výsledek<br>(Result)   | Rozsah hodnoty [mV]<br>(Range) |      | Výsledek<br>(Result) |
| Na                      | 495   | 516  | 506  | 203                            | 212  | 207.8                |
| K                       | 371   | 386  | 379  | 152                            | 159  | 155.4                |
| Ca                      | 123   | 128  | 126.5  | 50                             | 53   | 51.9                 |
| Cl                      | 247   | 258  | 252.9  | 101                            | 106  | 103.8                |
| Vodivost (Conductivity) | 4270  | 5220 | 5023   | 5690                           | 6970 | 6634                 |

## Test s roztoky – testovací kazeta (testovací roztok) (Basic fluidic test)

| Vodivost (Conductivity)                | Rozsah hodnoty [adc-csv]<br>(Range for mean) | Výsledek<br>(Result) | Rozsah stability [adc-csv]<br>(Range for SD) | Výsledek<br>(Result) |
|--|--|----------------------|--|----------------------|
| Cal1 trasa roztoku CAL1 (Cal1 fluidic) | 8000–10000                                   | 8862                 | <30  | 17.19                |
| Cal2 trasa roztoku CAL2 (Cal2 fluidic) | 5500–7500                                    | 6401                 | <30  | 12.37                |

## Výstupní test (montážní linka) (Final test)

|                |   |
|----------------|---|
| Splněno (Done) | (datum a podpis) 29.9.2022<br>(date and signature) Dlanke |
|----------------|---|

## Test se vzorky (QC laboratoř) (Final system QC)

|                |  |
|----------------|--|
| Splněno (Done) | (datum a podpis) 29.9.2022<br>(date and signature) Buzianová |
|----------------|--|

## Konečné operace (Closing activities)

| Popis (Description)  | Modul (Module)      | Kritéria (Limit) | Výsledek (Status) |
|--|---------------------|------------------|-------------------|
| Vložení rozpěrek do ventilů a uvolnění krytu pumpy<br>(Insert spacers into valves, release the pump cover) | Přístroj (Instrum.) | OK/ nOK          | ✓                 |
| Čištění a kontrola přístroje (vzhled, barva, vady – škrábance...) (Cleaning and Optical check)             | Přístroj (Instrum.) | OK/ nOK          | ✓                 |
| Balení přístroje (Packing)   | Přístroj (Instrum.) | OK/ nOK          | ✓                 |

Datum (Date): 30.9.2022

Podpis (Signature): Komentář: (Comment):  
.....  
.....  
.....

Erba Lachema s.r.o.

VYHOVUJE

EC 90



Materiál: 10020690

Šarže: 4457-2-202209 Exp: 03.10.2032

Číslo atestu: 12201959

S. B. 02 ku

Erba<sup>®</sup>  
Mannheim

EC 90

QC PROTOCOL

SN 04457 SW: v1.13.3

25/04/2023 09:00

TEST#: 000232  
TYPE: Plasma/Serum  
LEVEL: 2  
LOT: S062244

Na: 169.7 mmol/l OK  
[ 152.0 - 188.0 ]  
K: 6.33 mmol/l OK  
[ 5.81 - 7.13 ]  
Cl: 132.1 mmol/l OK  
[ 116.0 - 140.0 ]

*[Handwritten signature]*  
*[Handwritten date: 25/04/23]*

Erba<sup>®</sup>  
Mannheim

EC 90

QC PROTOCOL

SN 04457 SW: v1.13.3

26/04/2023 07:55

TEST#: 000233  
TYPE: Plasma/Serum  
LEVEL: 2  
LOT: S062244

Na: 169.4 mmol/l OK  
[ 152.0 - 188.0 ]  
K: 6.35 mmol/l OK  
[ 5.81 - 7.13 ]  
Cl: 130.3 mmol/l OK  
[ 116.0 - 140.0 ]

*[Handwritten signature]*  
*[Handwritten date: 26/04/23]*

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*[Handwritten date: 26/04/23]*