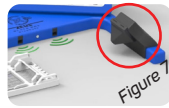


**Barcode Reader :** Enables the scanning of barcoded tubes at the final stage of the biopsy procedure, ensuring that the data are recorded in the system and securely stored (Figure 7).



## 11 ADVANCED DISH CONTROL FEATURES

### a. DISH-TO-DISH TRANSFER VERIFICATION

The system continuously monitors and verifies both the source dish/droplet and the target dish/droplet during embryo transfer.

- Operates using an old dish–new dish transition logic, eliminating transfer errors.
- Immediately alerts the user and halts the process** if an incorrect dish or droplet is detected.
- Allows continuation only after the error has been corrected.
- Stores comprehensive log data and video recordings of all actions.

### b. INITIAL SELECTION ORDER MANAGEMENT

**At the start of the procedure,** the user defines the initial dish selection order.

The system automatically manages all subsequent transfer operations in strict accordance with this predefined sequence.

## 12 BIOSAFE MODULE WORKFLOW

### a. POST-BIOPSY EMBRYO TUBING PROTOCOL

The BioPSafe embryo biopsy dish, positioned in a designated area of the BioPSafe carrier plate, can be removed and transferred to an inverted microscope or incubator. The biopsy dish is ergonomically designed to enable laser-assisted or mechanical embryo biopsy under an inverted microscope and includes a dedicated oil-free washing area.

#### Workflow Steps

- Embryos scheduled for biopsy are transferred into the BioPSafe embryo biopsy dish, and biopsy procedures are performed under a micromanipulator.
- The biopsy dish is placed in its designated position on the BioPSafe Plate.
- The triage of the embryo and biopsy material located together within the same droplet is performed under system control. Error-free transfer of the embryo to its designated culture or cryopreservation droplet, and of the biopsy material to its corresponding PCR tube, is ensured through real-time sensor-based tracking of positional and sequence data. Positional and sequence information is displayed in real time on the tablet interface. Any deviation is immediately detected, the user is alerted, and the procedure is automatically halted; continuation is permitted only after the user has corrected the error.
- User input for aspirating (Pick-Up) the embryo or biopsy material from the corresponding position in the biopsy dish, as well as for

dispensing (Drop) it into the target location, is performed via foot pedals. This allows the embryologist to continue the procedure efficiently and ergonomically without removing their hands from the working area or performing additional manipulations.

### Transfer to Culture Dish

- Embryos are aspirated using the *Pick-Up* command.
- Embryos are deposited into predefined wells of the culture dish using the *Drop* command.
- The procedure is repeated for each embryo.
- Upon completion, the culture dish is returned to the incubator.

### Biopsy Material Handling

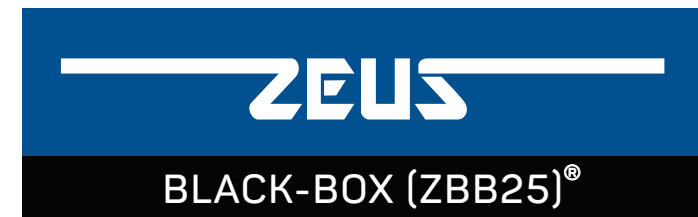
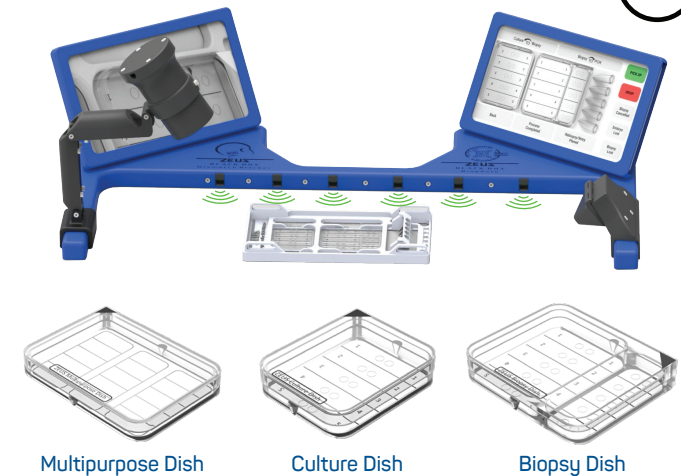
- PCR tubes are labeled with **patient-specific barcodes** prior to use.
- The embryo is transferred from the biopsy dish to its assigned droplet in the culture or cryopreservation dish.
- The biopsy material is transferred from the biopsy dish first to a washing droplet and then into the corresponding PCR tube.
- This process is repeated until each embryo and its associated biopsy material have been transferred to their designated droplets and PCR tubes.
- Through continuous sensor monitoring and final barcode verification of PCR tubes, the BLACK-BOX system ensures error-free matching and transfer between embryo, biopsy sample, and PCR tube.

### b. MULTI-PURPOSE MODULE WORKFLOW

- In Multi-Purpose mode, the system securely manages **droplet-to-droplet transfer** between dishes.
- Dish transfers performed on *Day 3 and Day 5* are automatically verified by the system.
- All procedures are documented in real time through tablet notifications and screen recordings.
- The system is fully compatible with **ICSI procedures**.

## 13 SAFETY & TRACEABILITY

- All procedures are recorded via Pick-Up and Drop commands.
- The tablet's front camera records the identity of the operator.
- Sensor systems continuously verify the accuracy of every user action and require user confirmation before proceeding to the next step.
- Barcode tracking ensures complete traceability between patient, embryo, and PCR tube.
- In the event of incorrect dish or droplet selection, the system immediately alerts the user, halts the procedure, and allows continuation only after corrective action.



# USER MANUAL

**ZEUS Bioscience**

+90 312 427 48 01

+90 530 336 03 52

info@zeusbioscience.com

www.zeusbioscience.com

## 1 DEVICE NAME, DESCRIPTION &

**Device Name** : ZEUS Black-Box Witness Systems  
**Device Description** : A comprehensive system designed to monitor, verify, and record all potential mismatches and errors associated with embryo biopsy and all other embryo manipulation procedures performed under a stereomicroscope.

- a. Authorized Company** : ZEUS Bioscience Biyomedikal A.Ş.  
**b. Producing Company** : ZEUS Bioscience Biyomedikal A.Ş.  
**c. Brand – Model** : ZEUS Black-Box - ZBB25

## 2 GENERAL WARNINGS

Read the User Manual carefully before using the device and take into consideration the indicated warnings.

This manual has been prepared for the safe, correct and productive use of the device you have received. The information and explanations that you will need to use the device are included in the manual. For the issue that cannot be solved you can contact the authorized company.

**Do not place/use the device on wet or damp surfaces. Use a properly grounded outlet when operating the device within a laminar flow cabinet.**

## 3 INTRODUCTION & GENERAL INFORMATION

The ZEUS Black-box is a system designed for use in embryology laboratories to enhance the reliability, control, and full digital traceability of all procedures performed under a stereo microscope within a laminar flow cabinet. The system operates in two distinct modes: **BioPSafe** and **Multi-Purpose**.

ZEUS Black-box is the first system uniquely designed to verify, during the embryo biopsy stage, that the embryo is transferred to the correct droplet and that the biopsy material is placed into the correct PCR tube. In addition, it enables the **secure, controlled, and fully traceable** management of culture processes, ICSI procedures, and all dish-to-dish transfer workflows.

### Technical Specifications:

Voltage / Amps: : 12 V / 3 A (Device) / 12 V / 1.5 A Foot Pedal  
 Device Dimensions: : 67 cm x 40 cm x 15 cm  
 Weight : 5 kg  
 Control Panel: : 8 inch Touch Screen Tablet (2 x)  
 Sensors: : 13 x Infrared Distance Sensors

All procedures are performed using **dishes specific to the carrier plate**.

## 4 INSTALLATION & USAGE

The device is delivered to the user in a shielded original box. Upon receipt, the device and all accompanying components must be checked against the box contents list provided in the user manual to ensure that no parts are missing. Before installation and operation, the user manual and the software guide must be read carefully. Installation and initial start-up are performed by the user. Place the

device on a suitable, stable worktop and never on wet or damp surfaces. The device must be connected to a properly grounded power outlet.

Install the device inside a laminar flow cabinet. The placement must be compatible with the connection of the stereo microscope. After positioning, perform device calibration. The calibration process takes approximately 4–5 minutes and is carried out according to the dish reference points on the plate.

Once calibration is complete, connect the foot pedal to the tablet on the right side via Bluetooth. After confirming that the entire system is operating correctly, the device is ready for use.

## 5 SHIPPING

The device is shipped within 5 days after payment. Shipping costs are paid by the user. Transport of the device will be done through licensed and accredited cargo companies. Regarding the issues that may occur during transportation the warranty and operation protocols of the transportation company shall be valid. Upon the request the device can be collected directly by the receiver.

## 6 FAULT FINDING & REMOVAL

In case of malfunction of the device, please contact the vendor. In the event of warranty coverage, the existing defective device shall be replaced by a new device. A replacement device will be shipped to your address within one week of receiving the returned device.

## 7 SECURITY RECOMMENDATIONS

- The user manual should be read carefully before using the device.
- The device should not be stored and used on wet and damp surfaces.
- The device should be stored and used in a laminar flow cabinet.
- Since the device has an electrically operated system, it should be used only by authorized persons with the necessary general safety precautions.

## 8 WARRANTY

The device is not covered by the warranty in case it was misused or used for other purposes. The user must check that all apparatus and parts are complete before installation. The user accepts that the manufacturer is not responsible for any damages, accidents, etc. that may occur during the installation and usage of the device. The buyer accepts these warranty terms when purchasing the product.

Details of the warranty conditions are stated in the warranty certificate which is delivered to the buyer after the device is approved by the seller.

## 9 DEVICE CONTENT

- 1 x Black-Box Console (includes 2 tablets)
- 2 x Power Adaptors
- 4 x Disposable Sterile Dish (2 x Multipurpose, 1 x Culture, 1 x Biopsy)
- 1 x Biopsy SLS Plate with PCR Tube Holder
- 1 x Multipurpose SLS Plate
- 1 x Foot Pedal
- 1 x Camera
- 1 x Barcode Reader
- 1 x User Manual
- 1 x Warranty Certificate
- 1 x Transport Bag

## 10 COMPONENTS

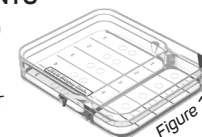
### a. MODULE COMPONENTS

	BIOSAFE MODULE	MULTI-PURPOSE MODULE
<b>Plate Used</b>	BioPSafe Plate. A carrier plate suitable for operation on a heated stage.	Multi-Purpose Plate. A carrier plate suitable for operation on a heated stage.
<b>Structure</b>	Aluminum plate designed to accommodate a <b>culture dish, a biopsy dish, and a PCR tube holder</b> .	Aluminum plate capable of holding <b>two multipurpose dishes</b> .

### b. DISH TYPES and SYSTEM COMPONENTS

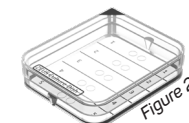
#### ii. Biopsy Dish

: A Petri dish in which embryo biopsy procedures are performed (Figure 1). It also includes a dedicated area for oil-free washing procedures.



#### Culture Dish

: A Petri dish to which embryos are transferred after biopsy and subsequently returned to incubation or cryopreservation (Figure 2).

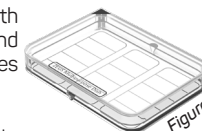


#### Tube Holder

: A specialized holder for barcoded PCR tubes. Its angled and ergonomic design enables precise transfer of embryo biopsy samples into PCR tubes under a stereo microscope (Figure 3).



**Multipurpose Dish**: A dish compatible with various biological and embryological procedures (Figure 4).



#### Foot Pedal

: Enables Pick-Up (aspiration into the pipette) and Drop (dispensing from the pipette) actions during embryo or cell transfer between dishes, allowing hands-free operation (Figure 5).



#### Tablet 1

: Procedure management and user control interface

#### Tablet 2

: A system that records and stores visual data related to users and performed procedures, integrated with a control interface.

#### Camera

: Records visual data of the performed procedures. The camera may be console-mounted or microscope-mounted, depending on user preference (Figure 6).

