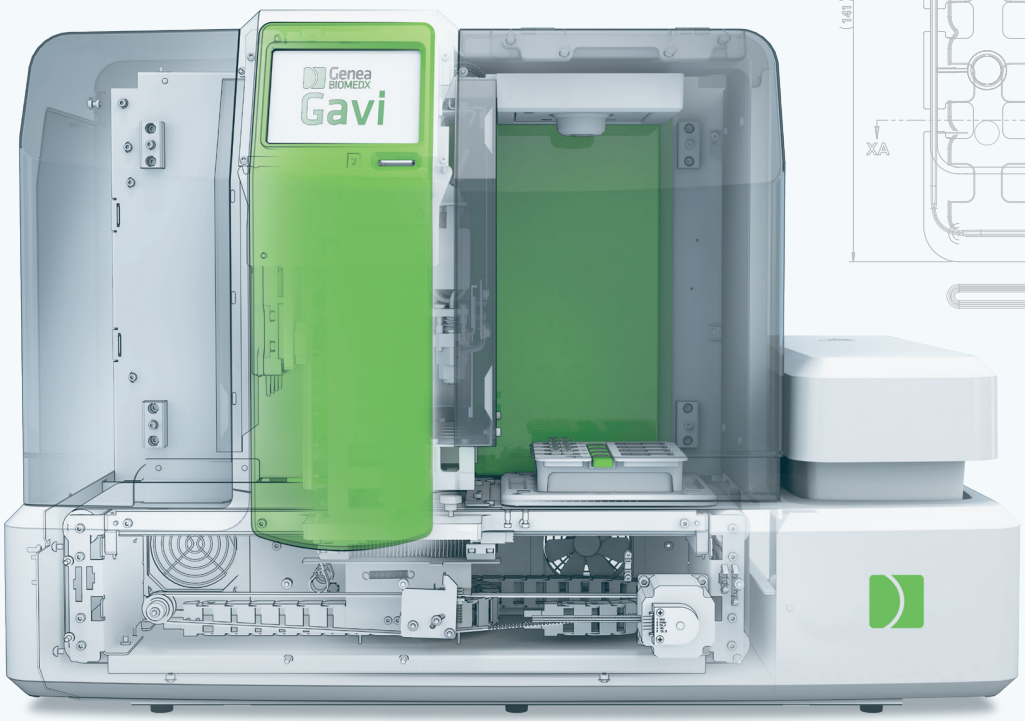
Genea BIOMEDX

Gavi

User Manual



GENERAL INFORMATION

Copyright

Technical Support

Manufacturer

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QUICK VIEW

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INTRODUCTION

It is the owner's responsibility to ensure that all users of Gavi have read and understood this user manual before operating the instrument.

This user manual is for readers who are familiar with clinical and laboratory techniques, instruments, and personal safety procedures and equipment. Before operating Gavi please ensure that you have the proper clinical and laboratory training.

Throughout this document where the Gavi Pod is referenced it should be noted that for the Oocyte and Zygote/Cleavage protocols up to two oocytes/zygotes/embryos can be held in the Gavi Pod. For the Blastocyst protocol one blastocyst can be held in the Gavi Pod.

Warnings & Cautions

The following warnings and cautions appear in the user manual. It is the owner's responsibility to ensure that all users of Gavi have read and understood these warnings and cautions before operating the instrument.

	**WARNING:** It is the owner's responsibility to ensure that all users of the Gavi: ▪ Are trained in all laboratory safety procedures, including the handling of liquid nitrogen and other hazardous materials ▪ Have read and understood the instructions and warnings contained in this user manual ▪ Have received adequate training in the correct operation of the Gavi.
	**WARNING:** For your safety, use only original Gavi consumables.
	**SINGLE USE ONLY:** The Gavi Pod, Gavi Tip & Seal Cartridge, and Gavi Medium Cartridge are consumables designed for single use only. Do not attempt to refill or reuse the consumables.

CAUTION:

- Gavi uses consumables that are light and heat sensitive and are subject to expiration dates. Make sure all consumables are correctly stored.
- Do not use the Gavi Pod, the Tip & Seal Cartridge, and the Medium Cartridge if they have passed their expiration dates or if the packaging appears damaged.
- Do not use the Gavi Pod and the Tip & Seal Cartridge if they appear to be damaged or look defective.
- Do not use the Medium Cartridge if the vials appear to have any leaks.
- Before use, the Gavi Medium Cartridge must be stored in the clear plastic packaging tray at all times to ensure traceability. It must be refrigerated at 2–8 °C and protected from light. Do not freeze.
- Store the Gavi Pods and the Tip & Seal Cartridges in a cool, dark, dry place.

See "About the Consumables" on page 10 for further instructions on the storage and use of the Gavi consumables.

WARNING:
Gavi contains no user serviceable parts. All repairs must be carried out only by an authorized service technician.

WARNING:
To reduce the risk of electric shock:

- Do not attempt to repair or modify any part of the instrument
- Do not remove any of the outer instrument panels or covers
- Do not place the instrument where it will be exposed to excessive moisture
- Do not touch any moving parts when the power is on or during operation
- The instrument must be connected to an earthed power outlet using only the supplied Power Cord
- Do not replace the supplied detachable mains supply Power Cord with an inadequately rated cord
- Connect the instrument only to an electrical power source with the proper voltage and frequency
- Disconnect the instrument from the power outlet before cleaning or Power Cord replacement
- Immediately replace the Power Cord if it becomes damaged, frayed, cracked or broken
- It is recommended that Gavi be connected to an uninterruptible power supply during operation.

WARNING:
To reduce the risk of injury, take care not to touch the Heat Sealer while loading the Operating Tray into Gavi.

	**WARNING:** Liquid nitrogen can cause serious injury or death. The following safety instructions DO NOT REPLACE your laboratory's or clinic's liquid nitrogen handling procedures. It is your responsibility to make sure that you are properly trained in the handling and use of liquid nitrogen.
	**CAUTION:** To reduce the risk of instrument damage: ▪ Do not open the Gavi Access Door while the LN_2 Bucket containing liquid nitrogen is being removed from or placed into the instrument.
	**WARNING:** ▪ Always take care when transferring or handling liquid nitrogen. ▪ Always wear personal protective equipment including: – eye and face protection – loose fitting, insulated gloves made to withstand cryogenic liquids. ▪ Never transfer liquid nitrogen directly from the primary pressurized tank into the Gavi LN_2 Bucket. ▪ Beware of splashing liquid and gas emissions when pouring liquid nitrogen. ▪ Do not overfill the Gavi LN_2 Bucket (see "Gavi LN2 Bucket" on page 19).
	**WARNING:** Oxygen deficiency meters and alarms must be used if you are operating the instrument in a confined space.
	**WARNING:** ▪ Always ensure that proper laboratory procedures are followed in the handling and disposal of hazardous materials. ▪ All blood products should be treated as potentially infectious.
	**WARNING:** ▪ Do not attempt to carry Gavi alone; the instrument weighs 59 kg. ▪ To minimize the risk of injury, Gavi should be carried by two people using the appropriate good-lifting and safe-carrying procedures.
	**WARNING:** Before use, inspect the Gavi Pod for debris or contamination. Discard the Gavi Pod if contaminated.
	**WARNING:** Liquid nitrogen can cause serious injury or death. Always follow your laboratory's or clinic's liquid nitrogen protocols and safety instructions.

	**WARNING:** ▪ Take care to adhere to aseptic techniques during all stages of the vitrification process. ▪ Take care when moving the oocytes/embryos with a glass pipette. Ensure a minimal transfer of media and avoid touching any of the plastic dishes with the pipette tips. ▪ Take care during all steps to minimize the creation of bubbles. ▪ Ensure that all tubes and culture dishes are suitable for use with embryos.
	**WARNING:** It is essential that all Gavi users are familiar with the entire Gavi process before using the instrument for the first time, in particular, preparing the Gavi Pods with VitBase and loading the oocytes/embryos. Before using Gavi for the first time: ▪ Practice preparing at least four Pods with VitBase (see "Preparing the Gavi Pods with VitBase" on page 31) ▪ Using the prepared Gavi Pods, practice loading blue beads or ethically approved oocytes/embryos to ensure correct placement in the Gavi Pod Divot (see "Loading the Oocytes/Embryos into the Gavi Pods" on page 33).
	**CAUTION:** Do not remove the Covers from the Tip & Seal Cartridge, or the Twist-Top Caps from the Medium Cartridge vials, until instructed.
	**CAUTION:** When fewer than four Gavi Pods are to be vitrified, the Gavi Pods should be arranged sequentially starting at the end closer to the Cassette's Label Area. For example, if two Gavi Pods are to be vitrified, the Gavi Pods must be placed only in Location A and Location B.
	**CAUTION:** To minimize the risk of evaporation: ▪ The following two sections (5.3.4. Final Instrument Preparation and 5.3.5. Preparing the Gavi Pods with VitBase) are to be completed within the five-minute period during which the oocytes/embryos are equilibrating in VitBase.
	**CAUTION:** ▪ Take care to avoid creating any bubbles when dispensing the VitBase into the GaviPods. Ensure that each Gavi Pod is evenly filled. ▪ Ensure that the Divot is full of VitBase and has no bubbles. If a bubble forms in the Gavi Pod Divot please discard the Gavi Pod and prepare a new one. ▪ The Pipette Tip Well must be filled properly with VitBase.
	**CAUTION:** To minimize the risk of evaporation: ▪ Complete the following steps to coincide with the end of the five-minute period during which the embryos are equilibrating in VitBase in the 37 °C un-gassed incubator.

	**CAUTION:** ▪ It is important to ensure the oocyte/embryo is placed and remains within the Gavi Pod Divot. Incorrect positioning of the oocyte/embryo may result in incorrect processing by Gavi. ▪ After placing all oocytes/embryos into their Gavi Pods, perform a final check to ensure correct positioning in the Gavi Pod Divot. If they have moved, return them to the specified Pod Divot position.
	**CAUTION:** The Gavi Pods contain only a small amount of solution and evaporation can occur. To avoid evaporation: ▪ Minimize the time taken when transferring the Cassette to liquid nitrogen ▪ The Cassette should be dunked into the liquid nitrogen within two seconds of removal from Gavi.
	**WARNING:** Take care to limit the exposure of the vitrified Gavi Pods to room temperature during moving and storage. Exposure time should be less than two seconds.
	**WARNING:** ▪ All Gavi users should be trained in the handling and use of liquid nitrogen.
	**WARNING:** ▪ Before your first time warming Gavi Pods, it is recommended that you are familiar with the entire Gavi process. ▪ Before warming for the first time, practice the protocol at least four times using Gavi vitrified blue beads or ethically approved oocytes/embryos, ensuring that all steps are completed in the appropriate time and that oocytes/embryos can be located.
	**WARNING:** When an Error Alert appears on Gavi, the first priority is the survival of the oocyte/embryo. Always return the oocyte/embryo to the VitBase dish if the error cannot be corrected within a short time.
	**CAUTION:** Do not attempt to clean any moving parts, wires or sensors, as damage may occur.
	**CAUTION:** ▪ To prolong the life of the instrument it is highly recommended that Gavi be powered off if it will not be used for longer than eight hours ▪ To guarantee safe operation, it is necessary to carry out proper maintenance of the instrument and accessories. Regular checks by the user are recommended to confirm correct functioning of the instrument.
	**CAUTION:** Federal Law (USA) restricts this device to sale by or on the order of a licensed physician or other healthcare practitioner.

Definition of Symbols

	Manufacturer
	Date of Manufacture
	Batch Code
	Serial Number
	Reference
	Use By
	Keep Away from Sunlight
	Sterile Using Irradiation
	Do Not Resterilize
	Single Use Only. Do Not Re-use
	Caution. Consult the User Manual
	Do Not Use if the Package is Damaged
	This Instrument is Subject to Laws Regarding the Disposal of Electronic Medical Equipment as Outlined in the WEEE Directive (2006/96/EC)
	Product conforms to the Medical Device Directive 93/42/EEC (BSI)
RxOnly	Federal Law (USA) restricts this device to sale by or on the order of a licensed physician or other healthcare practitioner

List of Icons

The following icons appear on the Gavi User Interface.

Icon	Description
	Blastocyst Protocol
	Zygote/Cleavage Protocol
	Oocyte Protocol
	Instrument Warming Up
	Start Protocol Run
	Abort Protocol Run
	Accept
	Cancel
	Access Home Screen
	Indicates Gavi Pod position on the Operating Tray
	Indicates Medium Cartridge position on the Operating Tray
	Indicates Tip & Seal Cartridge position on the Operating Tray
	Add. Used to indicate the number of Gavi Pods to be processed
	Subtract. Used to indicate the number of Gavi Pods to be processed
	Eject SD Card

	Access Gavi Settings Menu
	Access Service Settings
	Warning: Gavi Pod Error
	Warning: Medium Cartridge Error
	Warning: Tip & Seal Cartridge Error
	Warning: Gavi Door Close Error
	Warning: Lid Seal Error
	Warning: Liquid Nitrogen Error, Missing LN_2 Bucket
	Warning: SD Card Error, Missing or Full SD Card
	Warning: Temperature Error
	Active Warning
	Inactive Warning

1. SAFETY INSTRUCTIONS

WARNING:

It is the owner's responsibility to ensure that all users of the Gavi:

- Are trained in all laboratory safety procedures, including the handling of liquid nitrogen and other hazardous materials
- Have read and understood the instructions and warnings contained in this user manual
- Have received adequate training in the correct operation of the Gavi.

1.1. Perishables

WARNING:

For your safety, use only original Gavi consumables.

SINGLE USE ONLY:

The Gavi Pod, Gavi Tip & Seal Cartridge, and Gavi Medium Cartridge are consumables designed for single use only. Do not attempt to refill or reuse the consumables.

CAUTION:

- Gavi uses consumables that are light and heat sensitive and are subject to expiration dates. Make sure all consumables are correctly stored.
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- Do not use the Gavi Pod and the Tip & Seal Cartridge if they appear to be damaged or look defective.
- Do not use the Medium Cartridge if the vials appear to have any leaks.
- Before use, the Gavi Medium Cartridge must be stored in the clear plastic packaging tray at all times to ensure traceability. It must be refrigerated at 2–8°C and protected from light. Do not freeze.
- Store the Gavi Pods and the Tip & Seal Cartridges in a cool, dark, dry place.

See "About the Consumables" on page 10 for further instructions on the storage and use of the Gavi consumables.

1.2. Electrical

	**WARNING:** Gavi contains no user serviceable parts. All repairs must be carried out only by an authorized service technician.
	**WARNING:** To reduce the risk of electric shock: ▪ Do not attempt to repair or modify any part of the instrument ▪ Do not remove any of the outer instrument panels or covers ▪ Do not place the instrument where it will be exposed to excessive moisture ▪ Do not touch any moving parts when the power is on or during operation ▪ The instrument must be connected to an earthed power outlet using only the supplied Power Cord ▪ Do not replace the supplied detachable mains supply Power Cord with an inadequately rated cord ▪ Connect the instrument only to an electrical power source with the proper voltage and frequency ▪ Disconnect the instrument from the power outlet before cleaning or Power Cord replacement ▪ Immediately replace the Power Cord if it becomes damaged, frayed, cracked or broken ▪ It is recommended that Gavi be connected to an uninterruptible power supply during operation.

1.3. Heating

	**WARNING:** To reduce the risk of injury, take care not to touch the Heat Sealer while loading the Operating Tray into Gavi.

1.4. Liquid Nitrogen

	**WARNING:** Liquid nitrogen can cause serious injury or death. The following safety instructions DO NOT REPLACE your laboratory's or clinic's liquid nitrogen handling procedures. It is your responsibility to make sure that you are properly trained in the handling and use of liquid nitrogen.

CAUTION:

To reduce the risk of instrument damage:

- Do not open the Gavi Access Door while the LN_2 Bucket containing liquid nitrogen is being removed from or placed into the instrument.

1.4.1. Handling

WARNING:

- Always take care when transferring or handling liquid nitrogen.
- Always wear personal protective equipment including:
  - eye and face protection
  - loose fitting, insulated gloves made to withstand cryogenic liquids.
- Never transfer liquid nitrogen directly from the primary pressurized tank into the Gavi LN_2 Bucket.
- Beware of splashing liquid and gas emissions when pouring liquid nitrogen.
- Do not overfill the Gavi LN_2 Bucket (see "Gavi LN2 Bucket" on page 19).

1.4.2. Ventilation

WARNING:

Oxygen deficiency meters and alarms must be used if you are operating the instrument in a confined space.

Nitrogen is an asphyxiant. Rapid expansion of liquid nitrogen to gas is colorless, odorless, and tasteless and can quickly cause asphyxiation in confined spaces.

- Liquid nitrogen must be stored and used only in well-ventilated areas.
- Always use oxygen deficiency meters and alarms when using liquid nitrogen in confined spaces.

1.5. Hazardous Material

WARNING:

- Always ensure that proper laboratory procedures are followed in the handling and disposal of hazardous materials.
- All blood products should be treated as potentially infectious.

1.6. Electromagnetic Compatibility

Gavi has been tested and found to comply with the electromagnetic compatibility (EMC) limits for laboratory equipment as specified by EN 61326-1: 2013 (IEC 61326-1: 2012 Ed 2). These limits are designed to provide reasonable protection against harmful interference in a typical laboratory environment.

1.7. Installation & Maintenance

Installation, inspection, calibration and service of Gavi must be carried out only by an authorized service technician.

2. ABOUT GAVI

2.1. Indications for Use/Intended Use

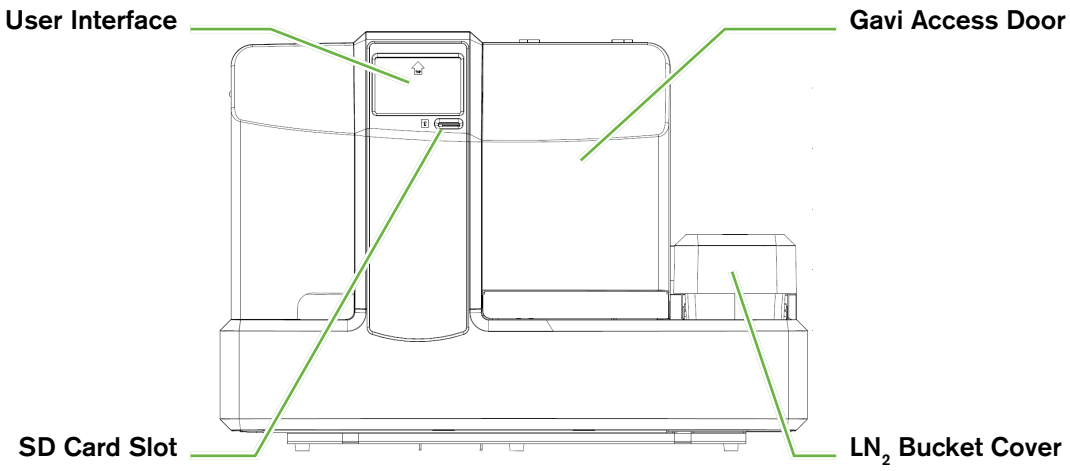
Gavi is intended for use in a clinic or laboratory environment for the preparation and vitrification of oocyte, zygote, cleavage and blastocyst stage embryos.

2.2. Instrument Description

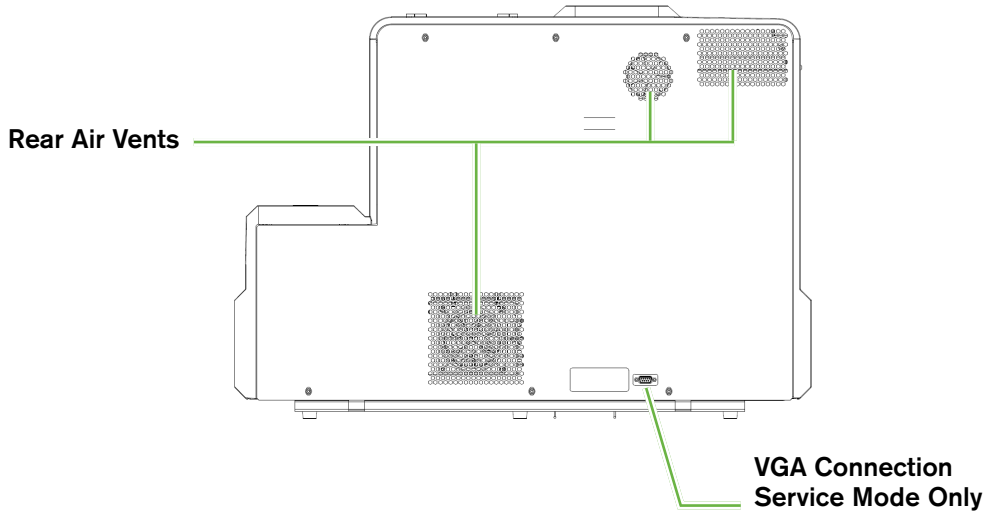
Gavi is designed to automate the equilibration steps in the vitrification process to minimize the variability that occurs during cryopreservation. This automated process reduces the potential for errors and ensures a standardized, repeatable procedure for vitrification in a controlled, closed-system environment. **NOTE:** The long-term safety of oocyte/embryo vitrification on children born following this procedure is unknown.

The instrument is operated through an intuitive touchscreen User Interface.

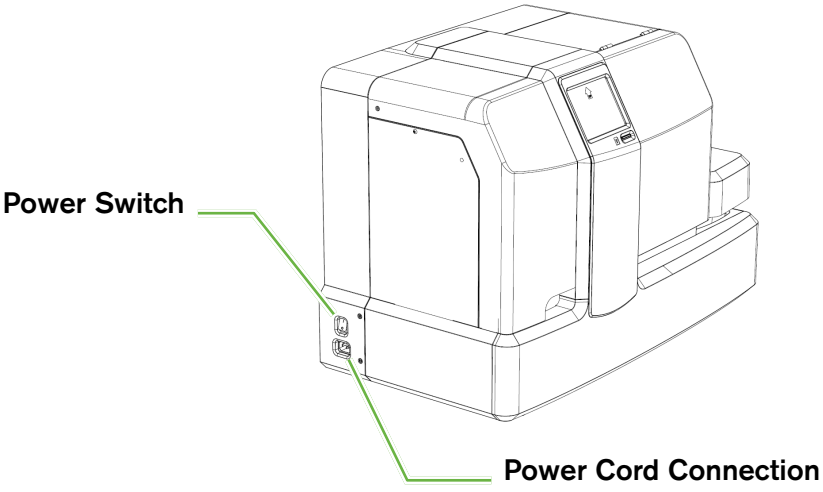
2.3. Front of the Instrument



2.4. Rear of the Instrument



2.5. Side of the Instrument



3. INSTALLATION & SETUP

3.1. Included Items

The following items are supplied with Gavi:

- The Gavi
- Power Cord (Country Specific)
- Gavi Operating Tray
- Gavi LN_2 Bucket
- Gavi Tweezers
- SD Card
- Gavi User Manual.

3.2. Instrument Installation

WARNING:

- Do not attempt to carry Gavi alone; the instrument weighs 59 kg.
- To minimize the risk of injury, Gavi should only be carried by two people using the appropriate good-lifting and safe-carrying procedures.

Gavi must be installed and tested only by an authorized service technician. During installation, testing and calibration of the instrument are performed to ensure correct operation.

- Gavi is designed for indoor use only.
- The instrument must not be moved or disconnected by unauthorized personnel.
- Do not open the shipping boxes if they appear damaged. Immediately contact your Genea Biomedx representative or authorized local service representative.

Installation requirements:

- A clean, controlled environment is essential for the correct operation of the instrument.
- The recommended ambient temperature range for the correct operation of the instrument is between 18 °C and 27 °C.
- Gavi must be placed on a sturdy, level surface away from air-conditioning outlets, heaters, excessive moisture or direct sunlight. The instrument must not be placed in proximity to flammable gases.
- To provide adequate ventilation, the minimum space requirement for Gavi is 0.9 m length by 0.7 m depth, with a minimum of 100 mm space at the rear of the instrument. The space should also have a clear height of 1.0 m to allow appropriate clearance to open and close the Gavi Access Door.
- It is highly recommended that an uninterruptible power source be used.

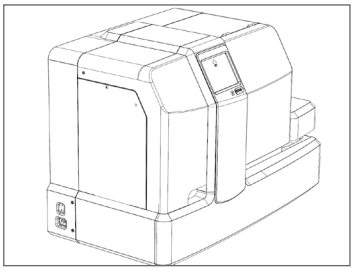
3.3. Instrument Settings

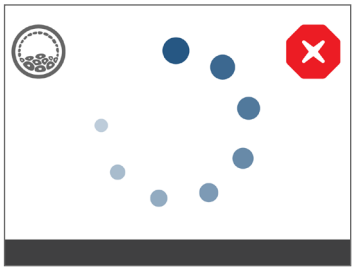
3.3.1. Powering On

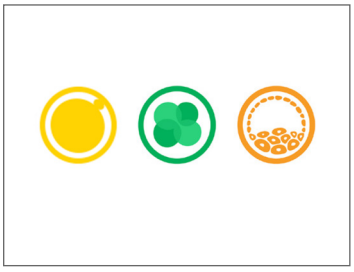
To power on Gavi:

1. Connect the Power Cord to Gavi's Power Cord Connection.
2. Connect the Power Cord to the mains power supply.
3. Switch mains power supply on.
4. Switch on Gavi's Power Switch.
5. Power on Gavi using the Power Switch located on the side of the instrument.

The Genea Biomedx logo will appear on the User Interface followed by the Warm-Up Screen. After Gavi has warmed up, the Home Screen is displayed.







3.3.2. Language Localization

The Gavi User Interface can display English, Japanese or Simplified Chinese language.

To localize the Gavi display language:

1. Tap Settings ⚙ from the Tool Bar on the Home Screen. The Settings Mode Screen will be displayed.
2. Tap Language from the Settings Mode Screen. The Language Screen will be displayed.
3. Tap the desired language to select. The Language Confirmation Screen will be displayed.
4. Tap [✓] to confirm the new language setting or [✕] to cancel. The Home Screen will be displayed.

3.3.3. Setting the Date & Time

To set the Date & Time:

1. Tap Settings ⚙ from the Tool Bar on the Home Screen. The Settings Mode Screen will be displayed.
2. Tap **Date & Time** from the Settings Mode Screen. The Date & Time Screen will be displayed.
3. Tap the corresponding [+] or [−] to select the current month, day and year.
4. Tap the corresponding [+] or [−] to select the current hour and minutes.
   NOTE: Gavi uses a 24-hour time format.

5. Tap [✓] to apply the new settings or [✗] to cancel.

Once the Date & Time settings have been confirmed, the Home Screen will be displayed.

NOTE: Gavi will not automatically update for local time conditions and will need to be manually adjusted for changes in time, such as daylight savings.

3.3.4. Installing & Removing the SD Card

Gavi records data logs of every Protocol Run performed on the instrument. These logs contain information about instrument parameters related to each Protocol Run, such as date and time, timings within the Protocol, and any errors that are detected.

The supplied SD Card has the capacity to hold over 10 000 individual logs. These logs are viewable on a computer equipped with an SD Card slot.

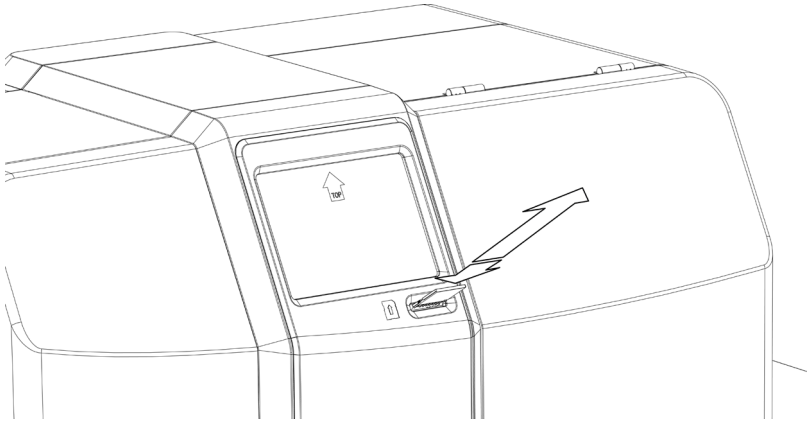
In the unlikely event that the card becomes full, simply replace the card with another SD Card of equivalent size. The SD Card must be formatted with a FAT32 file system and contain a volume label selected by the user. Always retain any full SD Cards in a safe and secure location for future reference.

To install the SD Card:

Insert the SD Card into the SD Card Slot at the front of the instrument and gently push into the slot until the card is securely held in place.

To eject and remove the SD Card:

1. Tap [SD] from the Gavi User Interface.
2. Tap [☑] to select Eject the SD Card.
3. Tap [☑] to confirm.
4. Push the SD Card gently into the slot and then release to physically eject the card.



4. ABOUT THE CONSUMABLES

4.1. General Information

4.1.1. Labeling Symbols

	Manufacturer
	Date of Manufacture
	Batch Code
	Serial Number
	Reference
	Use By
	Keep Away from Sunlight
	Sterile Using Irradiation
	Do Not Resterilize
	Single Use Only. Do Not Re-Use
	Caution. Consult the User Manual
	Do Not Use if the Package is Damaged
	This Instrument is Subject to Laws Regarding the Disposal of Electronic Medical Equipment as Outlined in the WEEE Directive (2006/96/EC)
	Product Conforms to the Medical Device Directive 93/42/EEC (BSI)
RxOnly	Federal Law (USA) restricts this device to sale by or on the order of a licensed physician or other healthcare practitioner

4.1.2. Quality Control

Each lot of consumables (Gavi Pod, Gavi Tip & Seal Cartridge, and Gavi Medium Cartridge) is tested for:

- Endotoxin by a limulus amebocyte lysate (LAL) test
  - Endotoxin level < 0.25EU/mL (except for the solutions in the Medium Cartridge < 0.4EU/mL)
- Biocompatibility by a mouse embryo assay (MEA) test
  - 1-cell ≥ 80% blastocyst
- Sterility
  - no growth detected

In addition, the solutions in the Medium Cartridge are tested for pH. All results are provided on lot specific Certificate of Analysis and are available upon request.

4.1.3. Storage & Stability

When correctly stored, Gavi consumables are stable until the expiration date shown on the product label. These products cannot be resterilized after opening.

Discard the consumables after use.

Do not use the consumables if:

- The packaging appears damaged or the seal is broken
- The solution appears turbid
- The expiration date has passed.

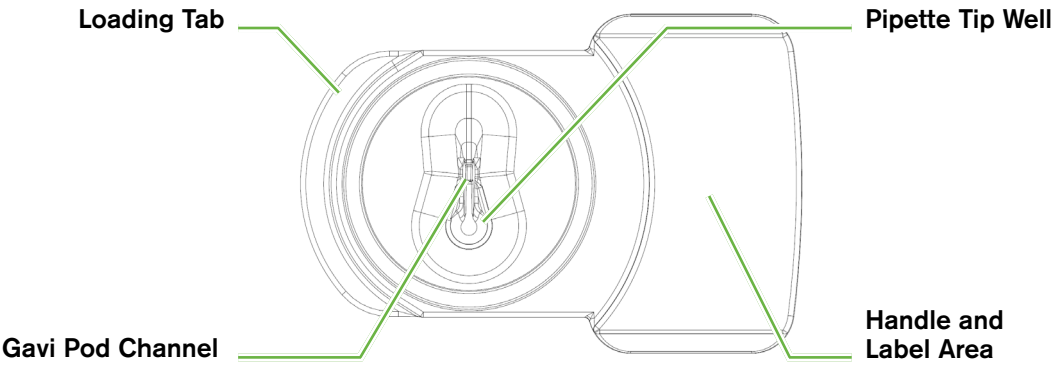
NOTE: See the individual consumables below for correct storage instructions.

4.1.4. Disposal

Dispose of the used Gavi consumables in accordance with your laboratory's procedures.

4.2. Gavi Pod

REF **GAVI-POD-20**



4.2.1. Indications for Use/Intended Use

The Gavi Pod must only be used in conjunction with the Gavi instrument. The Gavi Pod is a container with the capacity to hold two oocyte or zygote/cleavage stage embryos or one blastocyst stage embryo during the vitrification, storage and warming processes. While in the Gavi Pod and being processed by Gavi, oocytes/embryos are exposed to the cryoprotectant solutions for specific times and temperatures to equilibrate before vitrification. The instrument covers each Gavi Pod with a Lid Seal to create a closed system that prevents direct contact between oocytes/embryos and liquid nitrogen.

4.2.2. Consumable Provided

The Gavi Pod is supplied individually wrapped inside a pouch in a package of 20. Each Gavi Pod is sterile and is for single use only.

4.2.3. Storage & Stability

The Gavi Pods must be stored at room temperature, in their original sterile packaging. When correctly stored, Gavi Pods are stable until the expiration date shown on the product label. The Gavi Pods cannot be resterilized after opening and must be discarded after use. Do not use the Gavi Pods if the expiration date has passed or if the seal or packaging appears damaged or broken.

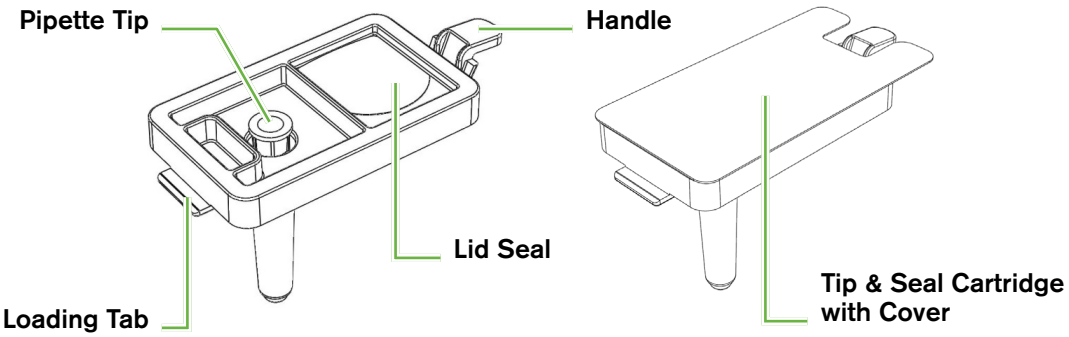
4.2.4. Preparation & Directions for Use

See “Preparing the Consumables & Accessories” on page 24.
See “Preparing the Gavi Pods & Cassette” on page 27.
See “Preparing the Gavi Pods with VitBase” on page 31.
See “Loading the Oocytes/Embryos into the Gavi Pods” on page 33.

⚠	**WARNING:** Before use, inspect the pod for debris or contamination. Discard the pod if contaminated.

4.3. Gavi Tip & Seal Cartridge

REF **GAVI-TIP-20**



4.3.1. Indications for Use/Intended Use

The Gavi Tip & Seal Cartridge is intended for use in Gavi. The Tip & Seal Cartridge contains the disposable Pipette Tip for dispensing the vitrification solutions into each of the Gavi Pods. The Cartridge also contains the Lid Seal to seal the Gavi Pod and prevent cross-contamination between samples.

4.3.2. Consumable Provided

The Gavi Tip & Seal Cartridge is supplied in a package of 20. It is supplied sterile and is for single use only.

4.3.3. Storage & Stability

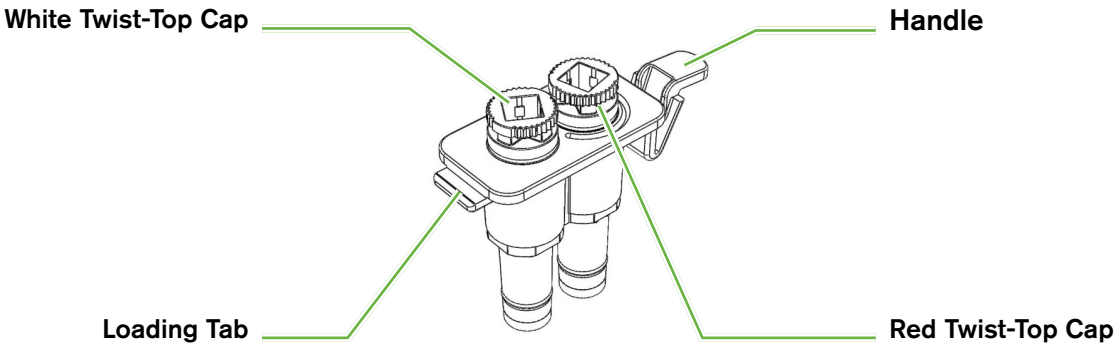
The Tip & Seal Cartridge must be stored at room temperature, in its original sterile packaging, away from direct sunlight.

4.3.4. Preparation & Directions for Use

See “Preparing the Consumables & Accessories” on page 24.

4.4. Gavi Medium Cartridge

REF **GAVI-MED-20**



4.4.1. Indications for Use/Intended Use

The Gavi Medium Cartridge is intended for use in Gavi. The Medium Cartridge comes preloaded with two vials containing ready-to-use vitrification solutions.

4.4.2. Consumable Provided

The Gavi Medium Cartridge contains two solutions:

- Gavi Solution 1 (contained in the vial with the white twist-top cap) is the equilibration solution supplemented with human serum albumin (16.8 mg/mL), dimethyl sulfoxide (DMSO) 8% and ethylene glycol 8%.
- Gavi Solution 2 (contained in the vial with the red twist-top cap) is the vitrification solution supplemented with human serum albumin (13.5 mg/mL), dimethyl sulfoxide (DMSO) 16%, ethylene glycol 16% and 0.68M trehalose.

The Gavi Medium Cartridge is supplied in a package of 20. It is supplied sterile and is for single use only.

4.4.3. Storage & Stability

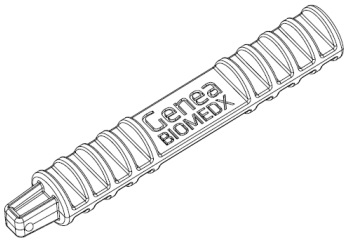
Before use, the Gavi Medium Cartridge must be stored in the clear plastic packaging tray at all times to ensure traceability. It must be protected from light and refrigerated at 2-8°C. Do not freeze.

4.4.4. Preparation & Directions for Use

See “Preparing the Consumables & Accessories” on page 24.

4.5. Gavi Vial Decapper

REF **GAVI-VDC-01**



4.5.1. Indications for Use/Intended Use

The Gavi Vial Decapper is intended to be used to remove the Twist-Top Caps from the Gavi Medium Cartridges.

4.5.2. Accessory Provided

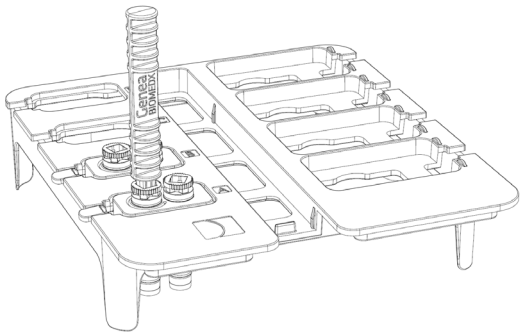
The Gavi Vial Decapper is supplied as a single unit.

4.5.3. Preparation & Directions for Use

The Gavi Vial Decapper is designed to fit securely into the Twist-Top Caps of the Gavi Medium Cartridges.

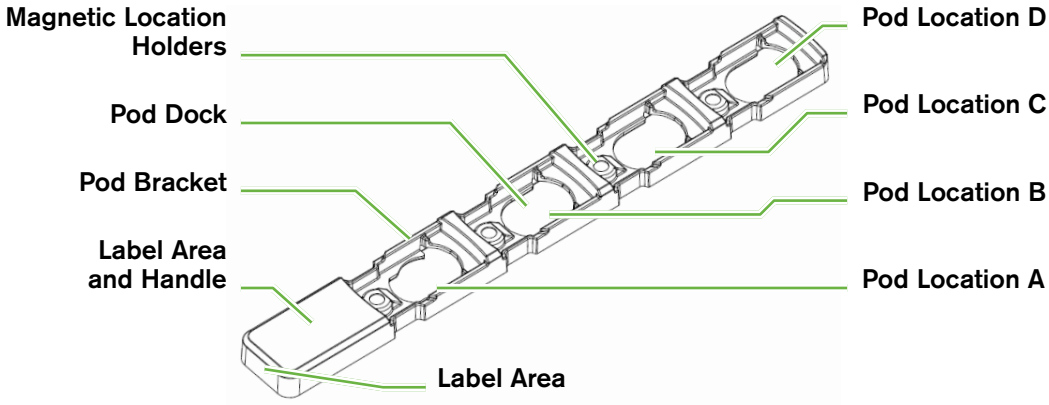
To Use:

Insert the Decapper's square end into the Twist-Top Caps of the Medium Cartridge. Rotate the Decapper counterclockwise to remove the Cap.



4.6. Gavi Cassette

REF **GAVI-CAS-20**



4.6.1. Indications for Use/Intended Use

The Gavi Cassette is intended for use in Gavi. The Cassette can hold up to four individual Gavi Pods for vitrification and long-term cryogenic storage. The Cassette's Handle has two Label Areas for patient identification.

4.6.2. Accessory Provided

The Gavi Cassette is supplied in a package of 20. It is supplied non-sterile and is for single use only.

4.6.3. Preparation & Directions for Use

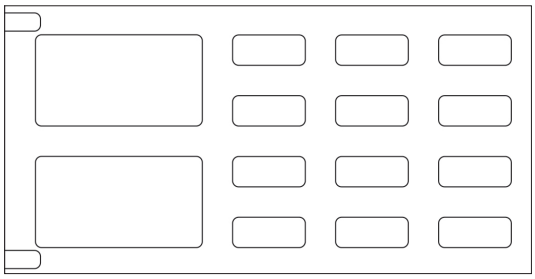
See "Preparing the Consumables & Accessories" on page 24.

See "Preparing the Gavi Pods & Cassette" on page 27.

See "Loading the Cassette into Gavi" on page 34.

4.7. Gavi Labels & Recommended Printer/Ribbon

REF GAVI-LAB-01



4.7.1. Indications for Use/Intended Use

The Gavi Labels are intended to be used to identify consumable/accessory items that are used in Gavi.

Each set of Gavi Labels has twelve small labels that can be used to label Gavi Pods and Cassettes, and two large labels that can be used to label Cassettes, dishes and documents.

4.7.2. Accessory Provided

Gavi Labels are supplied in a roll and packaged as a single unit. Each roll contains 700 sets of Gavi Labels and each set contains twelve small labels and two large labels.

4.7.3. Preparation & Directions for Use

Gavi Labels are compatible for use with Brady printer model BBP12 and Brady ribbon R7950.

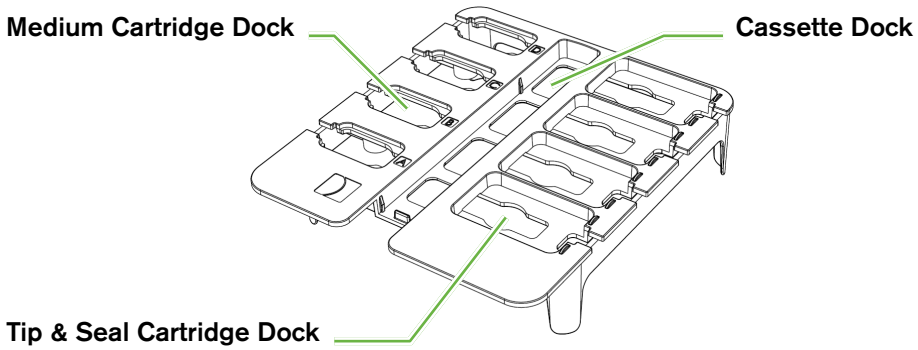
The printer should be set up and calibrated as per the instructions on the manufacturer's website: www.bradyid.com

For printer setup instructions download the 'Brady_BBP12_Printer_Setup.pdf' document from the manufacturers support page: www.qualityserviceandsupport.com/brady/article/7498

Gavi label software is available and provides a user interface screen to allow patient data entry for printing to the custom Gavi labels that are compatible with Genea Biomedx electronic witnessing device, Gidget.

4.8. Gavi Operating Tray

REF GAVI-TRA-01



4.8.1. Indications for Use/Intended Use

The Gavi Operating Tray is intended for use in Gavi. The Operating Tray is designed to hold the Cassette and Gavi Pods, Gavi Medium Cartridges and Tip & Seal Cartridges securely in place during instrument operation.

4.8.2. Accessory Provided

The Gavi Operating Tray is supplied and packaged as a single unit. The Gavi comes supplied with two Operating Trays.

4.8.3. Preparation & Directions for Use

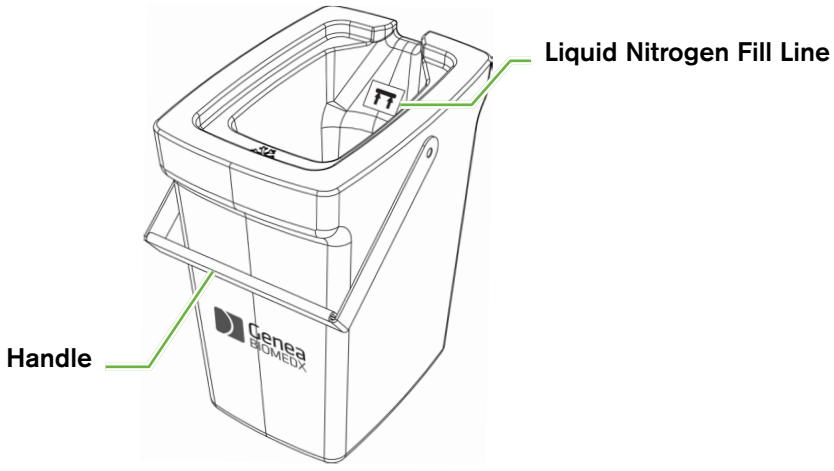
The Operating Tray is a reusable.

See “Preparing the Consumables & Accessories” on page 24.

For cleaning instructions see “QFRM168-11-012019” on page 19

4.9. Gavi LN_2 Bucket

REF GAVI-LN2-01



4.9.1. Indications for Use/Intended Use

The Gavi LN_2 Bucket is intended to hold liquid nitrogen. The Cassette and Gavi Pods are dunked into the liquid nitrogen contained in the LN_2 Bucket to complete the vitrification process. The LN_2 Bucket can be removed from the Gavi to transport the Cassette and Gavi Pods to long-term cryogenic storage.

4.9.2. Accessory Provided

The Gavi LN_2 Bucket consists of two parts: the bucket and the lid. It is supplied as a single unit. The Gavi comes supplied with one LN_2 Bucket.

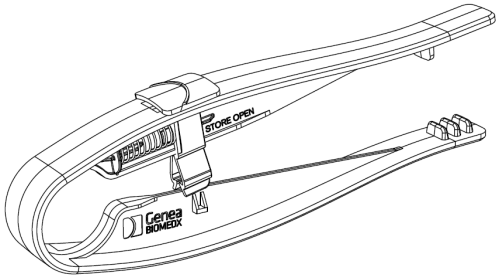
4.9.3. Preparation & Directions for Use

See “Preparing the Consumables & Accessories” on page 24.

	**WARNING:** Liquid nitrogen can cause serious injury or death. Always follow your laboratory’s or clinic’s liquid nitrogen protocols and safety instructions.

4.10. Gavi Tweezers

REF GAVI-TWE-01



4.10.1. Indications for Use/Intended Use

The Gavi Tweezers are intended to be used to hold the Cassette as it is dunked into the LN_2 Bucket.

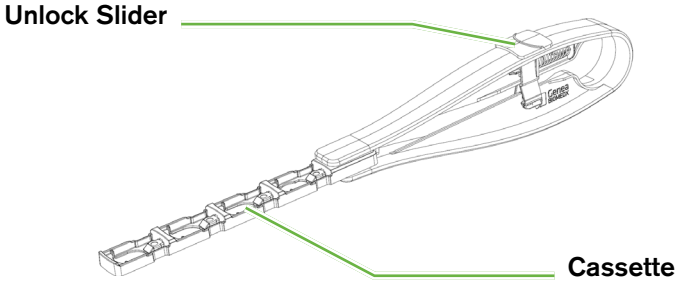
4.10.2. Accessory Provided

The Gavi Tweezers are supplied and packaged as a single unit. The Gavi comes supplied with one pair of Gavi Tweezers.

4.10.3. Preparation & Directions for Use

To hold the Cassette:

1. Position the Cassette Handle between the Tweezers' ribs. The Tweezers' ribs are designed to fit easily and securely onto the Cassette Handle.
2. To lock the Tweezers in place, squeeze the Tweezers together until in the locked position.



3. To release the Cassette, use your thumb to slide the Unlock Slider towards the back of the Tweezers. The Tweezers' ribs will open and release the Cassette.

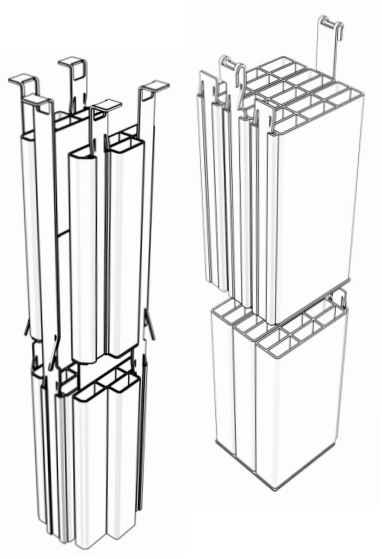
NOTE: When not in use, the Tweezers should be stored in the open, unlocked position.

4.11. Gavi Storage Dividers

REF **GAVI-SKA-01 (Round)**

REF **GAVI-SKB-01 (Square)**

Round Storage Dividers



Square Storage Dividers

4.11.1. Indications for Use/Intended Use

The Gavi Storage Dividers are intended to be used with cryogenic storage canisters to provide an orderly organization of Cassettes and Gavi Pods.

There are two types of Canister Divider Kits:

- Round Kit to fit a 67 mm or 70 mm round canister
- Square Kit.

4.11.2. Accessory Provided

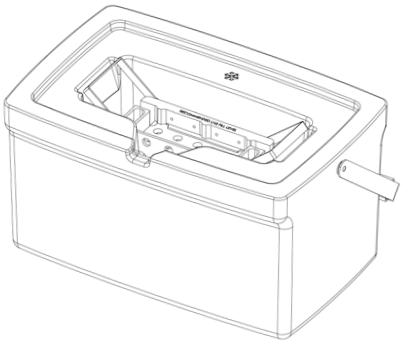
Each type of Storage Divider Kit is supplied and packaged as a box of 6.

4.11.3. Preparation & Directions for Use

The Storage Divider Kits are placed in the cryogenic storage canisters. The Dividers are designed to allow two levels of Dividers to be stacked in the same storage canister.

4.12. Gavi Working Station

REF **GAVI-WST-01**



4.12.1. Indications for Use/Intended Use

The Gavi Working Station is intended to hold liquid nitrogen and is used to assist the removal of Gavi Pods from the Cassette.

4.12.2. Accessory Provided

The Gavi Working Station consists of three parts: the Working Station bucket, a lid, and a metal block designed to fit in the bucket to provide a platform for the placement of the Cassette and Gavi Pods. The Working Station is supplied as a single unit.

WARNING:
Liquid nitrogen can cause serious injury or death. Always follow your laboratory's or clinic's liquid nitrogen protocols and safety instructions.

5. PREPARING GAVI FOR VITRIFICATION

*Refer to **QRTM6 Gavi Vitrification Process Cheat Sheet** for supporting information.*

⚠	**WARNING:** ▪ Take care to adhere to aseptic techniques during all stages of the vitrification process. ▪ Take care when moving the oocytes/embryos with a pulled pipette. Ensure a minimal transfer of media and avoid touching any of the plastic dishes with the pipette tips. ▪ Take care during all steps to minimize the creation of bubbles. ▪ Ensure that all tubes and culture dishes are suitable for use with oocytes/embryos.
⚠	**WARNING:** It is essential that all Gavi users are familiar with the entire Gavi process before using the instrument for the first time, in particular, preparing the Gavi Pods with VitBase and loading the oocytes/embryos. Before using Gavi for the first time: ▪ Practice preparing at least four Gavi Pods with VitBase (see 'Preparing the Gavi Pods with VitBase' on page 31) ▪ Using the prepared Gavi Pods, practice loading blue beads or ethically approved oocytes/embryos to ensure correct placement in the Gavi Pod Divot (see 'Loading the Oocytes/Embryos into the Gavi Pods' on page 33).

5.1. List of General Equipment Needed

The following is a list of the general equipment needed for the preparation of the Gavi consumables and accessories:

- Pipettes with sterile tips suitable for moving oocytes/embryos
- Pipette with flexible tip capable of dispensing 2 µL
- Patient identification labels (see "Gavi Labels & Recommended Printer/Ribbon" on page 17) or xylene-free permanent marker
- Safety goggles
- Cryogenic protective gloves
- Liquid nitrogen
- Liquid nitrogen storage Dewar
- VitBase solution
- Two 4-well culture dishes
- Microscope with a non-heated stage
- Gavi Pods
- Gavi Cassettes
- Gavi Tip & Seal Cartridges
- Gavi Medium Cartridges
- Gavi Tweezers
- Gavi Operating Tray
- Gavi Storage Dividers already in liquid nitrogen storage Dewar
- 37 °C incubator with gas off
- Timer with count-up function.

5.2. Preparing the Consumables & Accessories

5.2.1. Preparing the VitBase Dishes for Oocyte/Embryo Equilibration

To prepare the VitBase Dishes:

1. Prepare and label a 4-well culture dish.
2. Add 500 µL of VitBase to each required well (for example, if three Gavi Pods are to be vitrified, add 500 µL of VitBase to each of the three wells).
3. Place the dish into a 37 °C non-gassed incubator and allow sufficient time for the VitBase to equilibrate to 37 °C.
4. Prepare and label the second 4-well culture dish.
5. Add 500 µL of VitBase to a single well.
6. Place the dish onto the benchtop and allow sufficient time for it to warm to room temperature.

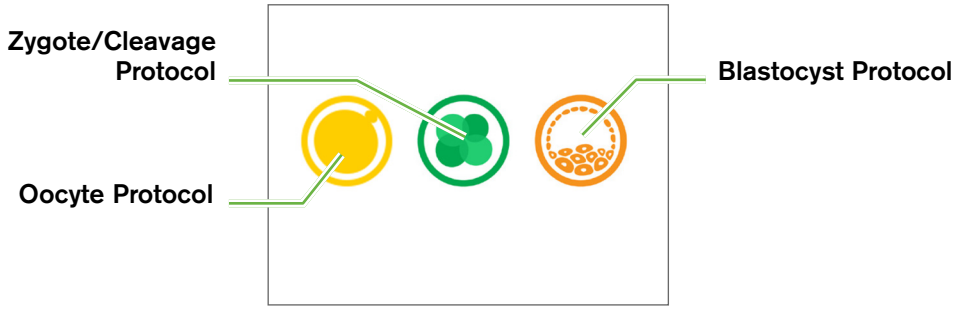
5.2.2. Power On Gavi

To power on Gavi:

1. Switch on Gavi using the Power Switch located on the side of the instrument.

The Genea Biomedx logo will appear on the User Interface followed by the Warm-Up Screen. After Gavi has warmed up, the Home Screen is displayed.

2. Tap the desired Protocol icon from the Home Screen. Gavi will begin an internal warm-up process.



While Gavi is warming up, continue with the preparation of the Operating Tray in 5.2.3. Preparing the Operating Tray.

5.2.3. Preparing the Operating Tray

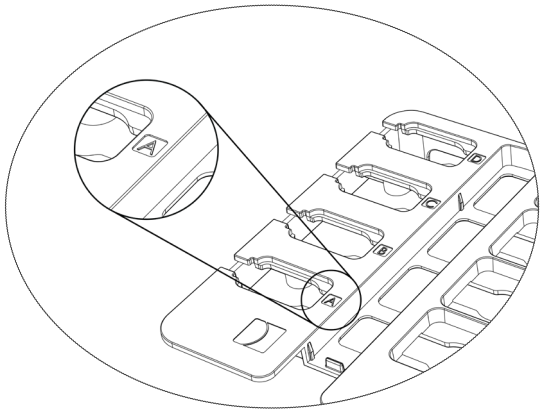
CAUTION:
Do not remove the Covers from the Tip & Seal Cartridge, or the Twist-Top Caps from the Medium Cartridge vials, until instructed.

The following items are required to prepare the Operating Tray:

- Gavi Operating Tray
- Gavi Medium Cartridge (select the same number of Cartridges as there are Gavi Pods to be vitrified)
- Gavi Tip & Seal Cartridge (select the same number of Cartridges as there are Gavi Pods to be vitrified).

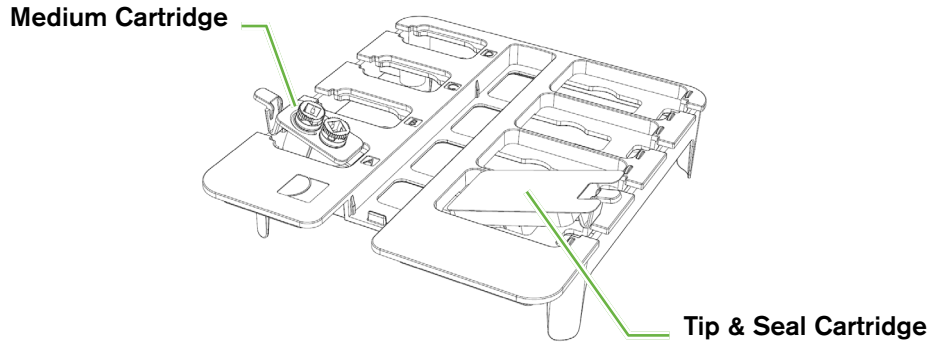
NOTE:

- To ensure traceability, the Gavi Medium Cartridges should be loaded into the Gavi Operating Tray directly from the clear plastic packaging tray.
- Each Gavi Pod to be frozen needs a Gavi Medium Cartridge and a Gavi Tip & Seal Cartridge.
- Always load Location A first (see below), when loading the Medium Cartridges and Tip & Seal Cartridges into the Operating Tray.



To prepare the Operating Tray:

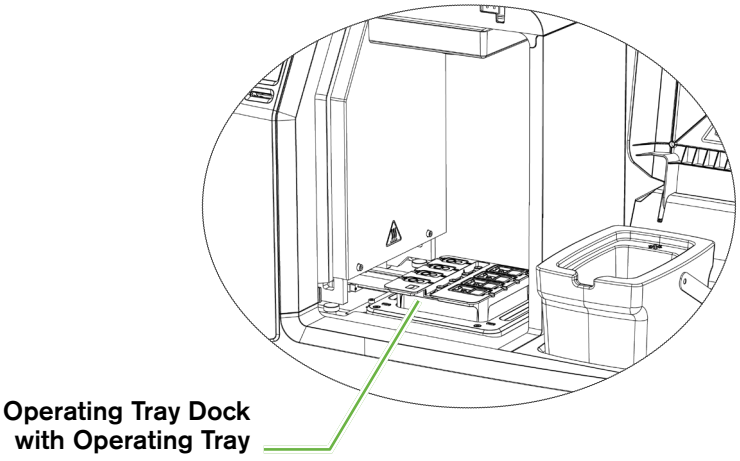
1. Load each Tip & Seal Cartridge into the Operating Tray's Tip & Seal Cartridge Dock so that the Cartridge's Loading Tab sits just below the Operating Tray's top, and the Tip & Seal Cartridge Handle clicks gently into place.
2. Load each Medium Cartridge into the Operating Tray's Medium Cartridge Dock so that the Cartridge's Loading Tab sits just below the Operating Tray's top and the Medium Cartridge Handle gently clicks into place.



5.3. Loading the Operating Tray into Gavi

To Load the Operating Tray:

Open the Gavi Access Door and gently place the Operating Tray over the Gavi Operating Tray Dock.

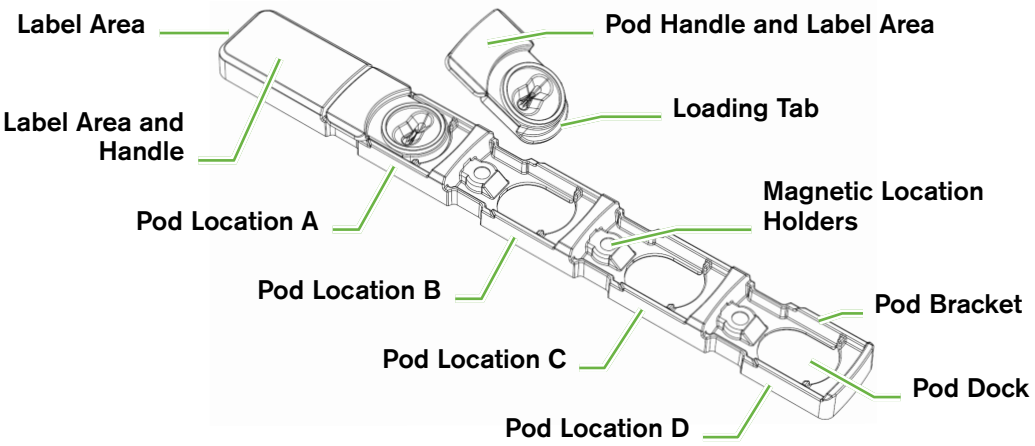


5.3.1. Preparing the Gavi Pods & Cassette

⚠	**CAUTION:** When fewer than four Gavi Pods are to be vitrified, the Gavi Pods should be arranged sequentially starting at the end closer to the Cassette's Label Area. For example, if two Gavi Pods are to be vitrified, the Gavi Pods must be placed only in Gavi Pod Location A and Gavi Pod Location B.

The following items are required to prepare the Gavi Pods and Cassette:

- Gavi Pods (select the correct number of Gavi Pods as there are oocytes/embryos to be vitrified)
- Gavi Cassette
- Gavi Labels or xylene-free permanent marker.



To prepare the Cassette:

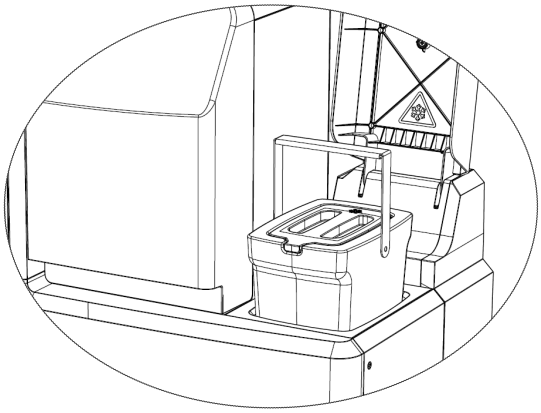
1. Remove each Gavi Pod to be used from its packaging.
2. Place Gavi Labels (or identification marks) on both Label Areas of the Cassette.
3. Place each Gavi Pod into the Cassette so that the Pod's Loading Tab sits inside the Cassette's Pod Bracket and the Pod Handle sits over the Magnetic Location Holder on the Cassette.
4. Place a Gavi Label (or identification mark) on the Label Area of each Gavi Pod to be used.
5. Place the Cassette onto the benchtop (to minimize the chance of debris falling into the empty Gavi Pods, the Cassette may be placed upside down on the benchtop).

5.3.2. Preparing the Gavi LN_2 Bucket

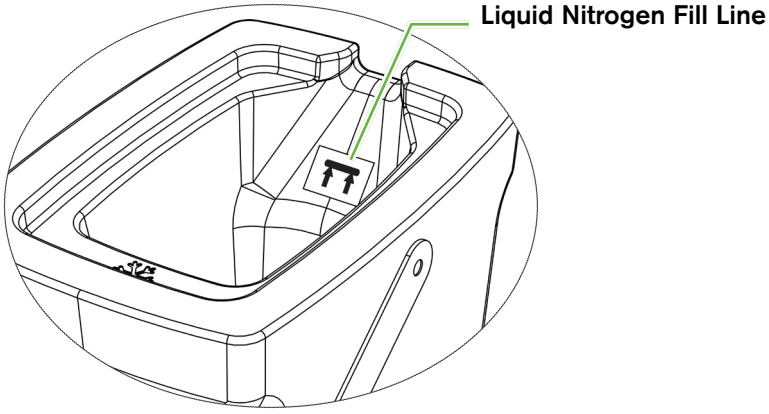
WARNING:
Liquid nitrogen can cause serious injury or death. Always follow your laboratory's or clinic's liquid nitrogen protocols and safety instructions.

To prepare the LN_2 Bucket:

1. Remove the LN_2 Bucket from Gavi and place it onto the benchtop.



2. Fill the LN_2 Bucket with liquid nitrogen up to the Liquid Nitrogen Fill Line (see below).



3. Return the LN_2 Bucket to Gavi.
4. Place the lid on the LN_2 Bucket to reduce liquid nitrogen evaporation.
5. Ensure that the Gavi Tweezers are within easy reach.

5.3.3. Equilibrating the Oocytes/Embryos in VitBase

VitBase is the initial holding solution for oocytes/embryos being processed by Gavi. Oocytes/embryos require equilibration in VitBase before being loaded into the Gavi Pods.

The following items are required to equilibrate the oocytes/embryos:

- Pipettes with sterile tips suitable for moving oocytes/embryos
- Microscope with non-heated stage
- 37 °C 4-well culture dish containing VitBase
- Timer with count-up function set to five minutes.

To equilibrate the oocytes/embryos:

1. Using a microscope with a non-heated stage, locate the oocytes/embryos to be vitrified.
2. Using a pipette with a sterile tip, retrieve an oocyte/embryo and transfer it to the 37 °C 4-well culture dish.
3. Repeat the above steps for any remaining oocytes/embryos. **NOTE:** If loading two oocyte or zygote/cleavage stage embryos, both can be placed in a single well.
4. Return the culture dish to the 37 °C un-gassed incubator.
5. Start the five-minute timer once the culture dish has been placed back in the incubator.

NOTE: The 4-well culture dish containing the oocytes/embryos should remain in the 37 °C un-gassed incubator for five minutes.

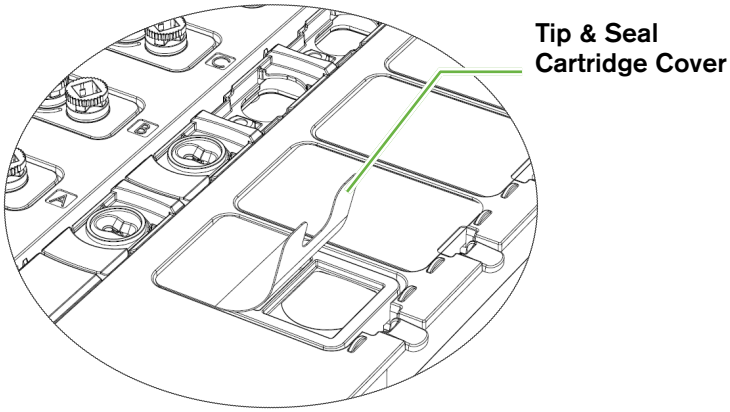
5.3.4. Final Instrument Preparation

CAUTION:

To minimize the risk of evaporation:

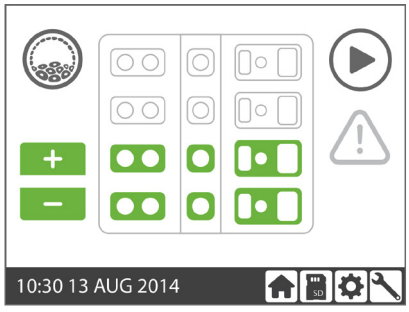
- The following two sections (5.3.4. Final Instrument Preparation and 5.3.5. Preparing the Gavi Pods with VitBase) are to be completed within the five-minute period during which the oocytes/embryos are equilibrating in VitBase.

1. Remove the Twist-Top Caps from the Medium Cartridge vials using the Gavi Vial Decapper.
2. Remove the Covers from the Tip & Seal Cartridges.



When Gavi has finished the automatic warm-up, a **Check LN_2 Filled** warning message will appear on the User Interface.

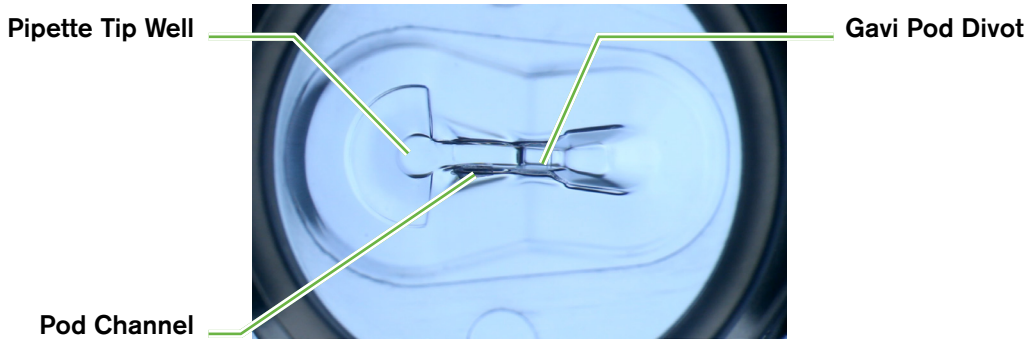
3. Check that there is sufficient liquid nitrogen in the LN_2 Bucket to reach the Liquid Nitrogen Fill Line.
4. Tap ☑ to confirm that the liquid nitrogen level in the LN_2 Bucket has been checked.
5. Tap + or − to select the number of Gavi Pods to be vitrified. Based on the number of Gavi Pods selected, the Operating Tray will be displayed on the Gavi User Interface with the corresponding consumables highlighted. The example below shows the Protocol Ready Screen with two Gavi Pods ready to be vitrified.



5.3.5. Preparing the Gavi Pods with VitBase

⚠	**CAUTION:** ▪ Take care to avoid creating any bubbles when dispensing the VitBase into the Gavi Pods. Ensure that each Gavi Pod is evenly filled. ▪ Ensure that the Divot is full of VitBase and has no bubbles. If a bubble forms in the Gavi Pod Divot please discard the Gavi Pod and prepare a new one. ▪ The Pipette Tip Well must be filled properly with VitBase.
⚠	**CAUTION:** To minimize the risk of evaporation: ▪ Complete the following steps to coincide with the end of the five-minute period during which the oocytes/embryos are equilibrating in VitBase in the 37 °C un-gassed incubator.

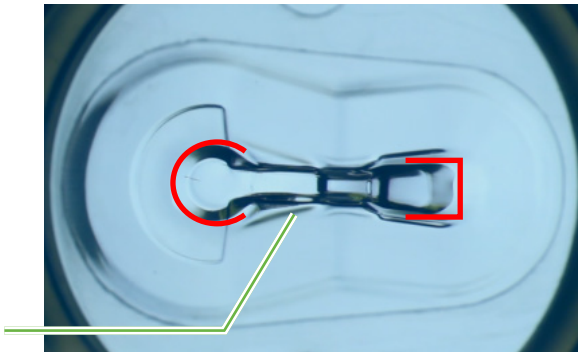
1. Retrieve the previously prepared 4-well culture dish containing the 500 µL of VitBase at room temperature.
2. Retrieve the previously prepared Cassette and Gavi Pods and place under a microscope.
3. Set the pipette with the flexible tip to 2 µL and aspirate 2 µL of room-temperature VitBase into the dish using the pipette's second stop.



4. Place the pipette tip into the Gavi Pod Divot.
5. Slowly fill the Gavi Pod Channel, ensuring that no bubbles are created (see the note and image on the following page).
6. Continue to dispense the remaining 2 µL (to the first pipette stop), by dragging the pipette tip left across to the Pipette Tip Well and then back right to cover the entire Gavi Pod Channel.
7. Using the same pipette with the flexible tip, repeat steps 3–6 above for all the remaining Gavi Pods in the Cassette.

(See the note and image on the following page)

NOTE: To ensure the VitBase fills the entire Gavi Pod Channel (the area between the red lines in the image below), gently drag the pipette tip around the edge of the Gavi Pod Channel. After the VitBase is added to the Gavi Pod it will appear as in the following image.



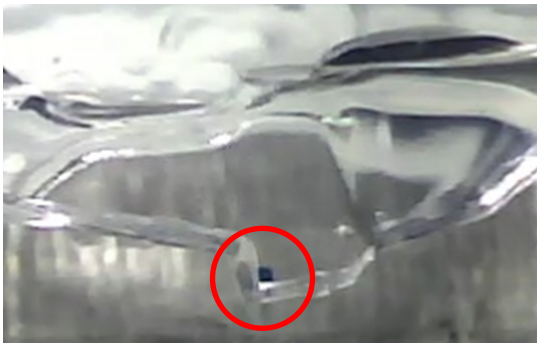
Gavi Pod Channel with VitBase

5.3.6. Loading the Oocytes/Embryos into the Gavi Pods

⚠	**CAUTION:** ▪ It is important to ensure the oocyte/embryo is placed and remains within the Gavi Pod Divot. Incorrect positioning may result in incorrect processing by Gavi. ▪ After placing all oocytes/embryos into their Gavi Pods, perform a final check to ensure they have remained in the Gavi Pod Divot. If they have moved, return them to the specified Gavi Pod Divot position.

To load the oocytes/embryos into the Gavi Pods:

1. Retrieve the 37 °C 4-well culture dish containing the equilibrating oocytes/embryos and place the dish on the microscope stage.
2. Transfer the highest grade oocyte/embryo from the dish to the Gavi Pod located at Gavi Pod Location A. Place the oocyte/embryo so that it is positioned in the Gavi Pod Divot closest to the steep wall, as shown below. **NOTE:** If loading two oocyte or zygote/cleavage stage embryos, ensure that they are as close to each other as possible.



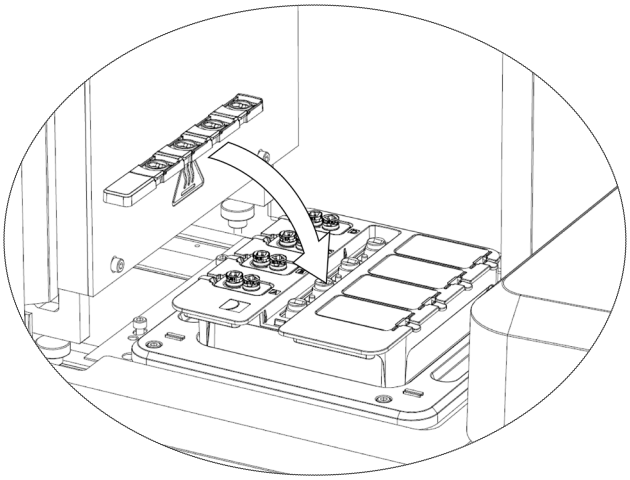
3. Transfer any remaining oocytes/embryos, placing the best embryo into the Gavi Pod at Gavi Pod Location B, the next-best embryo into the Gavi Pod at Gavi Pod Location C, and the final oocyte/embryo into the Gavi Pod at Gavi Pod Location D. Ensure that each embryo is correctly positioned in the Gavi Pod Divot.

NOTE: The Gavi Pod can hold up to two oocyte, zygote or cleavage stage embryos or one blastocyst stage embryo.

5.3.7. Loading the Cassette into Gavi

To load the Cassette:

1. Gently place the distal end of the Cassette into the Operating Tray Cassette Dock and lower the Cassette Handle onto the tray, ensuring that the Cassette sits flush against the back of the Operating Tray. The magnets in the Cassette and Gavi Pods will clip into place ensuring correct positioning.



2. Close the Access Door.

Gavi is now ready for the Protocol Run.

6. OPERATING GAVI

NOTE: Tap from the User Interface to abort the Protocol Run at any stage during the process.

6.1. The Protocol Run

	**CAUTION:** The Gavi Pods contain only a small amount of solution and evaporation can occur. To avoid evaporation: ▪ Minimize the time taken when transferring the Cassette to liquid nitrogen ▪ The Cassette should be dunked into the liquid nitrogen within two seconds of removal from Gavi.
	**WARNING:** Take care to limit the exposure of the vitrified Gavi Pods to room temperature during moving and storage. Exposure time should be less than two seconds.
	**WARNING:** Liquid nitrogen can cause serious injury or death. Always follow your laboratory's or clinic's liquid nitrogen protocols and safety instructions.

NOTE:

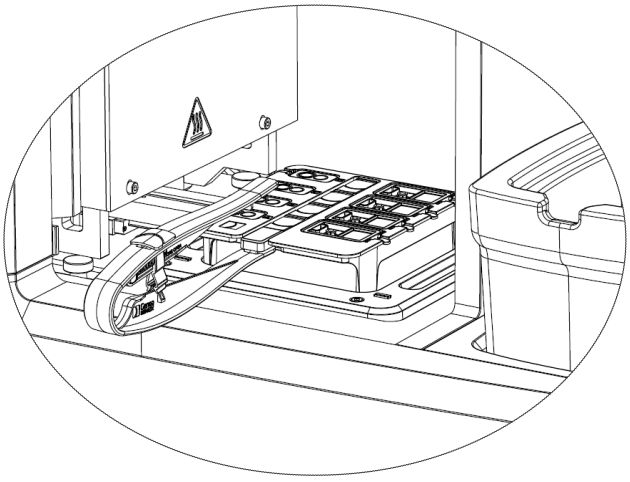
- Start the Protocol Run as soon as the Cassette is loaded into the Operating Tray.
- A Warning Alarm will sound approximately 30 seconds before the completion of the Protocol Run. When this first Warning Alarm sounds you must immediately return to the instrument.
- A second, continuous Warning Alarm will sound during the final 20 seconds of the Protocol Run and the User Interface will display the message *Stand by – protocol nearing completion.* As soon as the Protocol Run completes, the message is replaced by a timer showing the time elapsed since Protocol completion.
- As part of the Protocol Run, Gavi will automatically detect any loading or preparation errors. If any errors are detected Error Alerts will be displayed on the User Interface (see "Error Alerts" on page 44).

To start the Protocol Run:

1. Tap ▶ on the User Interface.

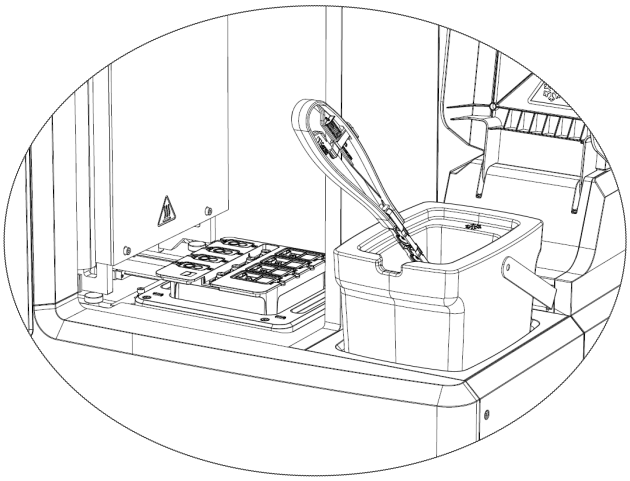
A countdown timer will be displayed on the User Interface showing the time remaining until Protocol completion.

2. When the first Warning Alarm sounds, immediately return to the instrument.
3. Open the LN_2 Bucket Lid and have the Gavi tweezers ready.
4. Listen for the second and final Warning Alarm.
5. When the second Warning Alarm sounds, open the Gavi Access Door and use the tweezers to retrieve the cassette from the Operating Tray.



6. Immediately dunk the cassette into the liquid nitrogen, ensuring all Gavi Pods are fully submerged.

7. Move the Cassette around the liquid nitrogen in a swirling motion for a minimum of five seconds.

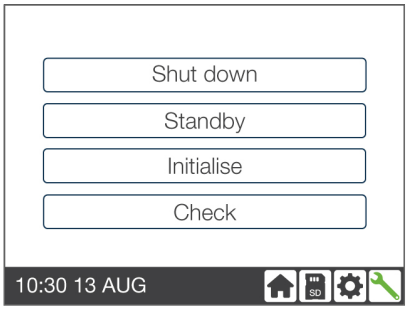


8. Release the Cassette into the LN_2 Bucket and replace the LN_2 Bucket Lid to minimize liquid nitrogen evaporation.
9. Tap ☑ on the **Remove and dunk cassette** dialogue box to confirm the Cassette has been submerged in LN_2.
10. Observe the dialogue box **Do not remove tray** and Tap ☑ on the User Interface to begin the Tip Eject process.
11. After the completion of the Tip Eject process, remove the Operating Tray from Gavi.
12. Tap ☑ on the **Remove waste and consumables** dialogue box.
13. Dispose of the Tip & Seal Cartridge and the Medium Cartridge.
14. When ready, remove the LN_2 Bucket and transfer the Cassettes to long-term storage Dewars.

6.2. Powering Off

To power off Gavi:

1. Tap from the User Interface.
2. Tap one of the shut-down options.



A pop-up window will then ask you to confirm the shut down of Gavi.

3. Tap ☑ to confirm or ☒ to cancel.

6.3. Standby Mode

If no selection is made from the Gavi Home Screen within 45 minutes, the instrument will go into Standby Mode. To prevent Gavi from entering Standby Mode, select the desired Protocol from the Home Screen. Once the Protocol is selected Gavi will begin an internal warm-up process.

7. GAVI POD WARMING PROCEDURE

Refer to QRTM7 and QRTM290 Gavi Pod Warming Procedure documents for supporting information.

When vitrified oocytes/embryos are required for transfer to a patient, warming is the procedure used to reverse the vitrification process.

	**WARNING:** ▪ Take care to adhere to aseptic techniques during all stages of the vitrification process. ▪ Take care when moving the oocytes/embryos with a glass pipette. Ensure a minimal transfer of media and avoid touching any of the plastic dishes with the pipette tips. ▪ Take care during all steps to minimize the creation of bubbles. ▪ Ensure that all tubes and culture dishes are suitable for use with oocytes/ embryos.
	**WARNING:** ▪ For oocyte warms calibrated equipment is required to maintain solutions at 37°C and ambient atmosphere e.g. heat stages/incubator. ▪ It is recommended calibration of equipment is performed periodically
	**WARNING:** ▪ All Gavi users should be trained in the handling and use of liquid nitrogen.
	**WARNING:** ▪ Before your first time warming oocytes/embryos vitrified using Gavi, it is recommended that you are familiar with the entire Gavi process. ▪ Before warming for the first time, practice the protocol at least four times using Gavi vitrified blue beads or ethically approved oocytes/embryos, ensuring that all steps are completed in the appropriate time and that oocytes/embryos can be located.

7.1. List of General Equipment Needed

The following is a list of the general equipment required for warming Gavi Pods:

- Pipettes with sterile tips suitable for aliquoting media and moving oocytes/embryos
- Patient identification labels or xylene-free permanent marker
- Safety goggles
- Cryogenic protective gloves
- Liquid nitrogen
- Liquid nitrogen storage Dewar
- Microscope with a calibrated heat stage set to maintain solutions at 37°C (for oocyte warming only)
- Microscope with a non heated stage (for cleavage/blastocyt warming)
- Gavi Working Station
- Gems Warming Set. NOTE: Recommended only for use as per Gems' Instructions

For Use

- Oocyte/embryo culture media
- Embryo culture oil
- Milli-Q®/Deionized/Tap water
- Calibrated timer
- Tweezers
- Kimwipes/Paper towels

7.2. Warming Setup Instructions

7.2.1. Preparation of Culture Dishes

Twenty-Four Hours Prior to Warming

Prepare sufficient dishes for oocyte/embryo culture according to your laboratory's established protocols.

On the Day of Warming

To prepare warm dishes:

1. Prepare and label a 4-well culture dish.
2. Add 500µL of Gems WarmSol 1 into well 1.
3. Add 500µL of Gems WarmSol 2 into Well 2.
4. Add 500µL of WarmSol 3 into well 3.
5. Add 500µL of WarmSol 3 into well 4.
6. Allow the solutions to equilibrate to 37°C for oocyte warming or room temperature for cleavage/blastocyst stage warming.
7. Prepare sufficient dishes for the number of Gavi Pods to be warmed. NOTE: It is recommended that each dish only be used for a maximum of two rounds of warming.

7.2.2. Preparation of Equipment

While the warming dish is equilibrating prepare the following equipment:

- Stereo microscope with the heated stage set to maintain solutions at 37°C (for oocyte warming)
- Stereo microscope with the heated stage off (for cleavage/blastocyst warming)
- Gavi working station with sufficient liquid nitrogen
- Water bath set to 37°C and placed as close as possible to the microscope
- P10 or P20 pipette set to 10 or 20µL with a sterile tip attached
- Wipes
- Tweezers
- Timer
- Suitable pipette for moving oocytes/embryos between warming solutions

7.3. Warming Instructions

7.3.1. Retrieval of the Gavi Pods to be Warmed

1. Using the Gavi LN_2 Bucket, retrieve the Cassette containing the Gavi Pods to be warmed from the long-term storage Dewar.
2. Place the Cassette onto the magnets on the side of the Gavi working station block.
3. Using tweezers retrieve the Gavi Pods to be warmed and place them onto the individual magnets of the Gavi working station block.

7.3.2. Warming Procedure: Oocyte Stage

NOTE:

- All steps post water bath (Steps 3. & 4.) should be performed on a calibrated heat stage/incubator (solutions at 37°C) and ambient atmosphere
- Steps 2–7 must be completed within 20 seconds.
- At step 9 oocytes may appear clear.

1. Remove the Pod to be warmed from the Gavi Working Station .
2. Preload a pipette with 20µL of equilibrated WarmSol 1 from well 1 of the prepared warming dish (perform this step immediately prior to pod dunk to mimimise temperature change – if any delays are experienced outside routine procedure timings discard WarmSol 1 and preload again)
3. Dunk the Pod into the water bath and move it around for 2–3 seconds.
4. Remove the Pod from the water bath and wipe off any excess water.
5. Place the Pod under the microscope.
6. Remove the Pod's foil Lid Seal.
7. Gently add 20µL WarmSol 1 from the preloaded pipette directly into the Pod's divot.
8. Leave the oocyte in the WarmSol 1 in the Pod for one minute.
9. During this one minute locate the oocyte. If necessary, change the microscope focal plane and light source angle to assist.
10. After one minute in WarmSol 1 in the Pod, transfer the oocyte to the WarmSol 1 in well 1 of the warming dish. **NOTE:** Release the oocyte at the bottom of the well and leave for one minute.
11. During the one minute in well 1, wash the pipette three times and then wash the oocyte three times.
12. Transfer the oocyte to the WarmSol 2 in well 2 of the warming dish and leave for three minutes.
13. Transfer the oocyte to the WarmSol 3 in well 3 of the warming dish and leave for five minutes.

14. Transfer the oocyte to the WarmSol 3 in well 4 of the warming dish and leave for one minute.
15. Transfer the oocyte to the prepared culture dish.
16. Follow your laboratory's established protocols for survival assessment.
17. Repeat the above steps for any remaining Pods to be warmed.

NOTE: The total time in WarmSol 1 of oocytes is two minutes.

7.3.3. Warming Procedure: Cleavage Stage

NOTE:

- All steps post water bath (3. & 4.) are performed at room temperature (RT) and ambient atmosphere
- Steps 2–7 must be completed within 20 seconds.
- At step 9 embryos may appear clear.

1. Preload a pipette with 10µL of equilibrated WarmSol 1 from well 1 of the prepared warming dish.
2. Remove the Gavi Pod to be warmed from the Gavi Working Station .
3. Dunk the Gavi Pod into the water bath and move it around for 2–3 seconds.
4. Remove the Gavi Pod from the water bath and wipe off any excess water.
5. Place the Gavi Pod under the microscope.
6. Remove the Gavi Pod's foil Lid Seal.
7. Gently add 10µL WarmSol 1 from the preloaded pipette directly into the Gavi Pod's divot.
8. Leave the cleavage stage embryo in the WarmSol 1 in the Gavi Pod for one minute.
9. During this one minute locate the embryo. If necessary, change the microscope focal plane and light source angle to assist.
10. After one minute in WarmSol 1 in the Gavi Pod, transfer the embryo to the WarmSol 1 in well 1 of the warming dish. **NOTE:** Release the embryo at the bottom of the well and leave for one minute.
11. During the one minute in well 1, wash the pipette three times and then wash the embryo three times.
12. Transfer the embryo to the WarmSol 2 in well 2 of the warming dish and leave for three minutes.
13. Transfer the embryo to the WarmSol 3 in well 3 of the warming dish and leave for five minutes.
14. Transfer the embryos to the WarmSol 3 in well 4 of the warming dish and leave for one minute.
15. Transfer the embryo to the prepared culture dish.

16. Follow your laboratory's established protocols for survival assessment.
17. Repeat the above steps for any remaining Gavi Pods to be warmed.

NOTE: The total time in WarmSol 1 of cleavage stage embryos is two minutes.

7.3.4. Warming Procedure: Blastocyst Stage

NOTE:

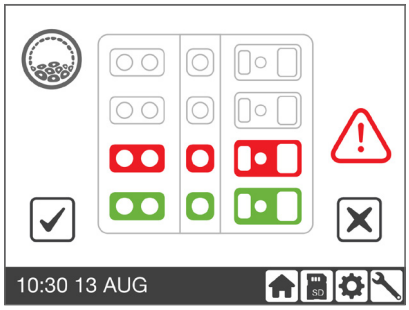
- All steps post water bath (3. & 4.) are performed at room temperature (RT) and ambient atmosphere
- Steps 2–7 must be completed within 20 seconds.

1. Preload a pipette with 10µL of equilibrated WarmSol 1 from well 1 of the prepared warming dish.
2. Remove the Gavi Pod to be warmed from the Gavi Working Station .
3. Dunk the Gavi Pod into the water bath and move it around for 2–3 seconds.
4. Remove the Gavi Pod from the water bath and wipe off any excess water.
5. Place the Gavi Pod under the microscope.
6. Remove the Gavi Pod's foil Lid Seal.
7. Gently add 10µL of WarmSol 1 from the preloaded pipette directly into the Gavi Pod's divot.
8. Leave the blastocyst in the WarmSol 1 in the Gavi Pod for one minute.
9. During this one minute locate the blastocyst. If necessary, change the microscope focal plane and light source angle to assist.
10. After one minute in the WarmSol 1 in the Gavi Pod, transfer the blastocyst to the WarmSol 2 in well 2 of the warming dish and leave for three minutes.
11. Transfer the blastocyst to the WarmSol 3 in well 3 of the warming dish and leave for five minutes.
12. Transfer the blastocyst to the WarmSol 3 in well 4 of the warming dish and leave for one minute.
13. Transfer the blastocyst to the prepared culture dish.
14. Follow your laboratory's established protocols for survival assessment.
15. Repeat the above steps for any remaining Gavi Pods to be warmed.

8. ERROR ALERTS

⚠	**WARNING:** When an Error Alert appears on Gavi, the first priority is the survival of the oocyte/embryo. Always return the oocyte/embryo to the VitBase dish if the error cannot be corrected within a short time.

8.1. Tray Loading Error Mode



The Tray Loading Error Alert indicates that the Gavi consumables (kits) either don't match the selection made on the User Interface, or the Medium Cartridge's Twist-Top Caps or the Tip & Seal Cartridge Covers have not been removed from the consumables on the Operating Tray. An optical sensor detects the presence of the required Tip & Seal Cartridges and Medium Cartridges. When Gavi identifies a missing consumable it displays the message, *Ensure selected kits are loaded correctly*.

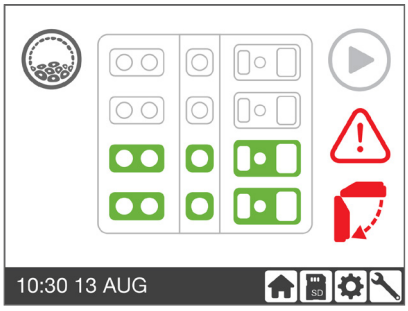
To correct:

1. Open the Gavi Access Door and immediately remove any Twist-Top Caps or Cartridge Covers that have not been removed.
2. Ensure that the number of GaviPods on the Operating Tray match the number of Gavi Pods selected on the User Interface.
3. Tap ☑ to restart the Protocol Run.
4. Tap ☒ to abort the Protocol Run.
5. Once the Protocol has finished, tap ☑ to proceed through the notification of the selected kit error.

NOTE:

- If the Protocol Run is restarted, Gavi will assume that the user has loaded any missing consumables and will run the Protocol for the number of Gavi Pods selected on the User Interface.
- If the Gavi consumables are correctly placed, then the optical sensor may be causing the issue. If this occurs, please contact your Genea Biomedx representative or authorized local service representative.

8.2. Door Close Error Mode



The Door Close Error Alert indicates that the Gavi Access Door is not closed.

If the Access Door is not properly closed, ensure there is nothing preventing the Access Door from closing and then close the door correctly.

NOTE: If the Access door is closed correctly, then the sensor may be causing the problem. If this occurs, please contact your Genea Biomedx representative or authorized local service representative.

8.3. Liquid Nitrogen Error Mode

The Liquid Nitrogen Error Alert indicates that the LN_2 Bucket has not been installed. Install the LN_2 Bucket by placing it into its correct position on the Gavi.

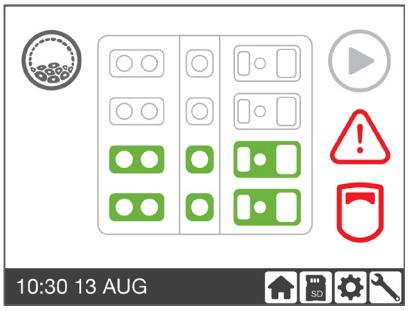
NOTE: If the LN_2 Bucket is already correctly placed on the instrument, then the sensor may be causing the problem. If this occurs, please contact your Genea Biomedx representative or authorized local service representative.

8.4. SD Card Error Mode

The SD Card Error Alert indicates that the SD Card is full or missing. If missing, install a new Card (see “Installing & Removing the SD Card” on page 9). In the unlikely event that the Card becomes full, replace it with another SD Card of equivalent size.

NOTE: The SD Card must be formatted with a FAT32 file system and contain a volume label selected by the user. Always retain any full SD Cards in a safe and secure location for future reference. If required, backup the SD Card and then reformat it.

8.5. Lid Seal Error Mode

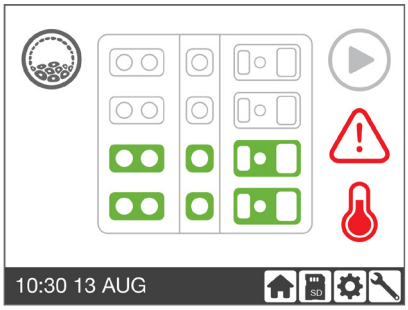


The Lid Seal Error Alert indicates that Gavi has detected a malfunction while in the process of transferring a Lid Seal onto a Gavi Pod.

At the completion of the Protocol Run, the Cassette and Gavi Pods should still be dunked into the liquid nitrogen.

NOTE: This error can occur either due to problems with the Lid Seal, such as a missing or damaged lid, or problems with the instrument. If this error occurs, please contact your Genea Biomedx representative or authorized local service representative.

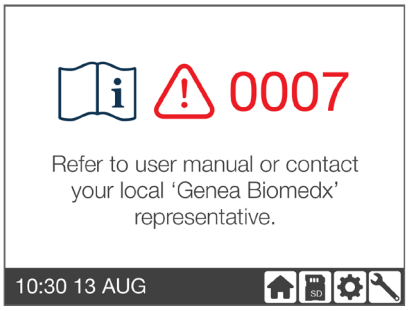
8.6. Temperature Error Mode



The Temperature Error Alert indicates that Gavi is outside the recommended normal operational temperature range, or the Peltier Module in Gavi is outside of its acceptable temperature range. Ensure that the room temperature is between 18 °C and 27 °C.

NOTE: If the room temperature is within the recommended range, then the sensor may be causing the issue. If this occurs, please contact your Genea Biomedx representative or authorized local service representative.

8.7. Critical Error Mode



The Critical Error Alert indicates that Gavi has detected a critical instrument malfunction. If this occurs, please contact your Genea Biomedx representative or authorized local service representative.

9. MAINTENANCE & SERVICE

9.1. After Each Use

	**CAUTION:** Do not attempt to clean any moving parts, wires or sensors, as damage may occur.
	**CAUTION:** ▪ To prolong the life of the instrument it is highly recommended that Gavi be powered off if it will not be used for longer than eight hours ▪ To guarantee safe operation, it is necessary to carry out proper maintenance of the instrument and accessories. Regular checks by the user are recommended to confirm correct functioning of the instrument.

9.2. Cleaning and Disinfection

The outer/inner surfaces of the Gavi instrument can be wiped down with purified water or a mild detergent solution. Always wear protective gloves (latex or nitrile) when cleaning Gavi.

As a guide, the following cleaning steps can be performed when necessary:

1. Remove all consumables from the instrument.
2. Power Off the instrument and remove the mains Power Cable from the wall socket.
3. Allow 15 minutes for the instrument to cool.
4. Apply purified water or a mild detergent solution to a clean disposable wipe.
5. Use the wipe to clean the surfaces of the instrument.
6. Allow to air dry.

Decontamination of device surfaces should be carried out immediately after media spills or when other contamination is visible. Effective decontamination comprises cleaning to remove visible soil and disinfection to provide a surface free from all forms of microbial life (except for large numbers of bacterial spores). The procedures described below are recommended when there is visual evidence of contamination/soiling and have been validated to demonstrate their effectiveness.

Cleaning the device:

1. Cleaning should be performed on an empty instrument (no embryos in place and the door open). Ensure that there is adequate lighting to visualize areas of contamination.
2. Remove visible contamination with a low shedding absorbent wipe moistened with high purity water.

3. Moisten another low shedding absorbent wipe with highly purity water and wipe all accessible surfaces of the device.
4. Repeat the wiping step at least three times or until no residue is visible on the wipe. Use a new wipe for each repeat.
5. If the device is determined not to be visually clean, repeat steps 4. And 5. Until device is visually clean.
6. Leave access door open and allow 1 hour for moisture to dissipate and to appear dry.
7. Proceed to disinfection.

Disinfection of the device:

1. Disinfection should be performed on an empty instrument (no embryos in place and access door open)
2. Moisten a low shedding absorbent wipe with 70% isopropyl alcohol and wipe all accessible surfaces of the device.
3. Repeat step 2. At least three more times, using a new wipe for each repeat.
4. Leave the access door open and allow 1 hour for alcohol fumes to dissipate and to appear dry.

9.3. User Maintenance Test

NOTE: The User Maintenance Test is to be completed by the user, not by the authorized service technician.

In order to ensure optimal Gavi performance, regular inspections are necessary for early detection of possible malfunctions. A User Maintenance Test must be conducted on a quarterly basis (see “User Maintenance Test” on page 52). In addition, if an instrument is relocated in the laboratory or moved for cleaning purposes a User Maintenance Test is recommended to check system integrity.

9.4. Decontamination

If the Gavi is to be returned to the manufacturer or scrapped, the instrument will require decontamination. Decontamination must be carried out by an authorized service technician or an approved Genea Biomedx delegate.

9.5. Servicing Gavi

Gavi must undergo an annual maintenance service by an authorized service technician.

10. TECHNICAL SPECIFICATIONS

10.1. Instrument Specifications

Protocol Run for up to four Gavi Pods simultaneously	
Closed system free from liquid nitrogen contamination	
Precision dispense accuracy down to 1 µL	
Operational ambient temperature	18 °C to 27 °C
Operational altitude	< 2 000 m above sea level
Electrical rating	100–240 V ~ 50/60 Hz 3.2–1.5 A
Operating humidity	20–80%
Dimensions	795 mm width x 568 mm height x 417 mm depth
Weight	59 kg
User Interface	Touchscreen
Mains fuse	Fast Blow 5 A 250 V AC

10.2. Consumable/Accessory Specifications

Vitrification	>11 000 °C/min
Warming	>8 000 °C/min
Medium Cartridge vial solution volume	300 µL

10.3. Instrument Life

The life of the instrument is deemed to be five years. Genea Biomedx is not responsible for the instrument after this time period.

10.4. Technical Support

Manufacturer

Genea Biomedx Pty Ltd
Level 2, 321 Kent Street
Sydney New South Wales, 2000, Australia
Email: info@geneabiomedx.com
Web: www.geneabiomedx.com

Authorized European Representative

EC REP

DONAWA LIFESCIENCE CONSULTING SRL
Piazza Albania, 10
00153 Rome
Italy

11. USER MAINTENANCE TEST

In order to ensure optimal Gavi performance, regular inspections are necessary for early detection of possible malfunctions. A User Maintenance Test must be performed on a quarterly basis. In addition, if an instrument is relocated in the laboratory or moved for cleaning purposes a User Maintenance Test is recommended to check system integrity.

The Test consists of three runs of a Custom Protocol, with pauses included to allow for the assessment of fluid volumes . Volumes are visually assessed under a microscope and compared to User Maintence Test Record (11.11, Appendix A). The Gavi Pods are then dunked in liquid nitrogen before being warmed and peeled for visual assessment of the Gavi Pod Seals.

11.1. Equipment Required

- Liquid nitrogen (enough to fill the LN_2 Bucket)
- Water Bath at 37 °C
- Microscope with a non-heated stage
- Gavi Tweezers
- 2 x metal tweezers
- Stopwatch
- VitBase Solution (approximately 200 µL)
- Pipette with tip capable of dispensing 200 µL
- 36 mm culture dish
- Pipette with flexible 130 µm tip capable of dispensing 2 µL
- Disposable dry wipes
- Xylene-free permanent marker
- 4 x Gavi Medium Cartridges
- 3 x Gavi Cassettes
- 12 x Gavi Tip & Seal Cartridges
- 12 x Gavi Pods
- 3 x User Maintenance Test Record printouts (see “Appendix A: User Maintenance Test Record” on page 60).

11.2. Preparation

11.2.1. Preparing Gavi

1. Power on Gavi using the Power Switch located on the side of the instrument.
2. Tap  from the Tool Bar on the Home Screen.
3. Tap **Check**.
4. Tap **User Maintenance Test**.

Once the Protocol has been selected Gavi will take a few minutes to warm up and reach the Protocol Ready Screen. Continue with the following steps while Gavi warms up.

11.2.2. Preparing the Equipment

WARNING:
Liquid nitrogen can cause serious injury or death. Always follow your laboratory's or clinic's liquid nitrogen protocols and safety instructions.

1. Prepare the 37 °C water bath.
2. Place the stopwatch onto the benchtop (certain checks must be completed within time limits or evaporation may invalidate results).
3. Using a pipette, transfer 200 µL of VitBase to the 36 mm culture dish (this dish holds the VitBase used to fill the Gavi Pods).
4. Place the flexible pipette and the dish containing the VitBase next to the microscope.
5. Load the Gavi Operating Tray with four Gavi Medium Cartridges and four Tip & Seal Cartridges.
6. Remove the Twist-Top Caps from the Gavi Medium Cartridges.
7. Remove the LN_2 Bucket from Gavi and fill to the Liquid Nitrogen Fill Line with liquid nitrogen.
8. Return the LN_2 Bucket to its position on Gavi.
9. Place the Lid on the LN_2 Bucket to reduce liquid nitrogen evaporation.
10. Ensure that the User Maintenance Test Record printouts, and all other required items, are nearby.

11.3. Fluidics Checks & Vitrification

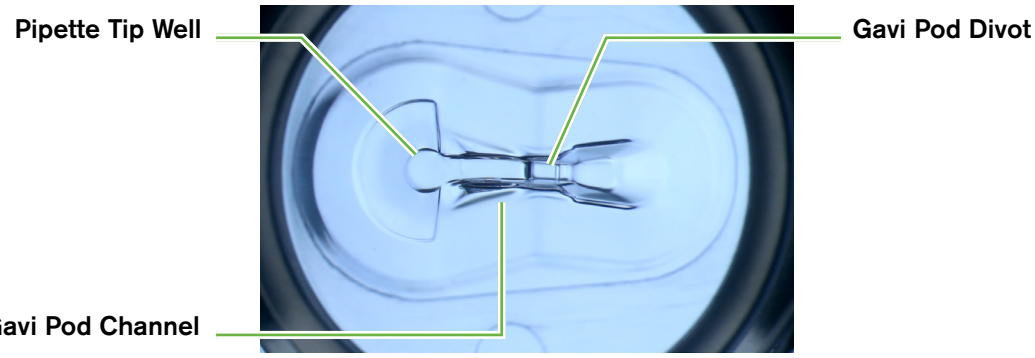
11.3.1. Preparing the Consumables

1. Load the Gavi Operating Tray with the four Gavi Tip & Seal Cartridges (leave Covers on at this stage).
2. Confirm the Gavi Operating Tray is loaded with the four Gavi Medium Cartridges with Twist-Top Caps removed.
3. Open the Gavi Access Door and gently place the Operating Tray over the Gavi Operating Tray Dock.
4. Carefully remove the Covers from the Gavi Tip & Seal Cartridges.
5. Check that the Lid Seals have remained seated in the Tip & Seal Cartridges.
6. Load a Gavi Cassette with four Gavi Pods.
7. Label the Gavi Pods according to the run number and Gavi Pod Location (for example, for the first run, label the Gavi Pods 1A, 1B, 1C and 1D. For the second

run, label the Gavi Pods 2A, 2B, 2C and 2D).

11.3.2. Preparing the Gavi Pods with VitBase

1. Set the pipette with the flexible tip to 2 µL and aspirate 2 µL of VitBase from the culture dish.
2. Place the pipette tip into the Gavi Pod Divot and slowly fill from the Divot Area, ensuring no bubbles are created.
3. Continue to dispense the remaining VitBase in the pipette by dragging the pipette tip left across to the Pipette Tip Well and then back right to cover the entire Gavi Pod Channel.

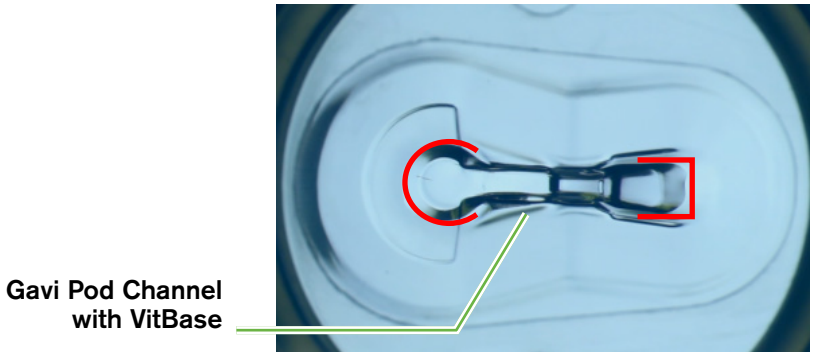


4. Repeat for the remaining three Gavi Pods.

Once all the Gavi Pods contain VitBase:

5. Insert the Cassette into Gavi.
6. Close the Access Door.

NOTE: To ensure the VitBase fills the entire Gavi Pod Channel (the area between the red lines in the image below), gently drag the pipette tip around the edge of the Gavi Pod Channel. After the VitBase is added to the Pod it will appear as in the following image.



11.4. Commencing the Protocol Run

From the Protocol Ready Screen:

1. Tap + four times until all four Gavi Pods are selected.
2. Tap ▶ to start the Protocol Run.

When Gavi displays the Run ID on the User Interface, copy it to the Gavi Run ID field in a new User Maintenance Test Record printout. Also enter the initials of the user conducting the Test in the Tester field.

11.5. Check Number One: Drain Volume

The stopwatch is used to time this Check.

1. Immediately start the stopwatch when Gavi beeps and displays Check #1 – Press when done.

Aim to complete the remaining steps in this Check within one minute.

2. Open the Access Door and transfer the Cassette to the microscope.
3. For each Gavi Pod, from A to D:
    a. Remove the Gavi Pod from the Cassette
    b. View the Gavi Pod under the microscope and tick which image it matches most closely in Check #1 of the User Maintenance Test Record printout
    c. Return the Gavi Pod back to its position on the Cassette.
4. When all the Gavi Pods have been assessed and returned to the Cassette, reinsert the Cassette back into the Operating Tray in Gavi.
5. Tap ▶ on the User Interface to resume the Protocol Run.
6. Stop the stopwatch and record the time in the Assessment Time field under Check #1 of the User Maintenance Test Record printout.

11.6. Check Number Two: Final Volume

The stopwatch is used to time this Check.

1. Immediately start the stopwatch when Gavi beeps and *Check #2 – Press when done* is displayed on the User Interface.

NOTE: Aim to complete the remaining steps in this Check within one minute.

2. Open the Access Door and transfer the Cassette to the microscope.
3. For each Gavi Pod, from A to D:
    a. Remove the Gavi Pod from the Cassette
    b. View the Gavi Pod under the microscope and tick which image it matches most closely in Check #2 of the User Maintenance Test Record printout
    c. Return the Gavi Pod back to its position on the Cassette.
4. When all the Gavi Pods have been assessed and returned to the Cassette, reinsert the Cassette back into the Operating Tray in Gavi.
5. Tap ▶ on the User Interface to resume the Protocol Run.
6. Stop the stopwatch and record the time in the Assessment Time field under Check #2 of the User Maintenance Test Record printout.

11.7. Sealing & Vitrification of the Gavi Pods

NOTE:

- A Warning Alarm will sound approximately 30 seconds before the completion of the Protocol Run. When this first Alarm sounds you must immediately return to the instrument.
- A second Warning Alarm will sound during the final 20 seconds of the Protocol Run.

1. Immediately return to Gavi when the first Warning Alarm sounds.
2. Open the LN_2 Bucket Cover and remove the LN_2 Bucket Lid.
3. When the second Warning Alarm sounds open the Gavi Access Door. (The Operating Tray should be seen moving back to its original position.)
4. When the Operating Tray has come to a complete stop, use the Gavi Tweezers to grip the Cassette Handle.
5. Remove the Cassette from the Operating Tray and immediately dunk the Cassette into the LN_2 Bucket, ensuring all Gavi Pods are completely submerged.
6. Move the Cassette around the liquid nitrogen in a swirling motion for a minimum of five seconds.
7. Release the Cassette from the Tweezers and replace the LN_2 Bucket Lid to minimize liquid nitrogen evaporation.
8. Observe the **Do not remove tray** dialogue box and Tap ☑ on the User Interface to begin the Tip Eject process.

9. After the Tip Eject process is complete, remove the Gavi Operating Tray from Gavi.
10. Discard used Gavi Tip & Seal Cartridges.
11. Keep Medium Cartridges for reuse in the next two Protocol Runs.
12. Repeat from Section 10.3. until a total of three Protocol Runs have been completed. When these runs have been completed the LN_2 Bucket should contain three Cassettes with a total of 12 Gavi Pods.

11.8. Warming & Seal Checks

11.8.1. Preparing the Workspace

1. Remove the LN_2 Bucket from Gavi and place it next to the water bath.
2. Remove the LN_2 Bucket Lid.

11.8.2. Warming the Gavi Pods

1. Using the metal tweezers, grip the Cassette holding the Gavi Pods from the first Protocol Run, while holding the other Cassettes apart from it. Ensure all Gavi Pods remain submerged in the liquid nitrogen while the Cassette is being gripped.
2. Quickly move the first Cassette out of the liquid nitrogen and into the water bath, ensuring all Gavi Pods are submerged in the water.
3. Stir the water with the Cassette for 2–3 seconds.
4. Remove the Cassette from the water.

11.8.3. Check Number Three: Pre-Peel Seal Check

1. Inspect the Gavi Pod Seal Lid on each of the Cassette's Gavi Pods. The Seals should be concave or flat (not convex or popped).
2. Record the result by ticking the appropriate box in Check #3 of the User Maintenance Test Record printout.

11.8.4. Check Number Four: Post-Peel Seal Check

1. For each Gavi Pod, from A to D:
    a. Remove Gavi Pod from the Cassette
    b. Wipe the Gavi Pod with a disposable dry wipe
    c. Peel the Gavi Pod Seal Lid using the Tab located on the Seal
    d. Inspect the Seal. The Seal should show a complete ring where the heat sealing took place, and there should be no water visible inside the Gavi Pod
    e. Record the result by ticking the appropriate box in Check #4 of the User Maintenance Test Record printout.
2. Repeat Section 10.8. for all the remaining Cassettes and Gavi Pods.

11.9. Pass/Fail Assessment

1. Review the completed User Maintenance Test Records and tally up the number of Outlier values for each position in each Check, User Maintenance Results Table below:

CHECK	CRITERIA	KIT A OUTLIERS	KIT B OUTLIERS	KIT C OUTLIERS	KIT D OUTLIERS
CHECK #1: DRAIN VOLUME	1 or less = PASS 2 or more = FAIL	__ + __ + __ = __ PASS ☐ FAIL ☐	__ + __ + __ = __ PASS ☐ FAIL ☐	__ + __ + __ = __ PASS ☐ FAIL ☐	__ + __ + __ = __ PASS ☐ FAIL ☐
CHECK #2: FINAL VOLUME		__ + __ + __ = __ PASS ☐ FAIL ☐	__ + __ + __ = __ PASS ☐ FAIL ☐	__ + __ + __ = __ PASS ☐ FAIL ☐	__ + __ + __ = __ PASS ☐ FAIL ☐
CHECK #3: PRE-PEEL SEAL CHECK	0 = PASS 1 or more = FAIL	__ + __ + __ = __ PASS ☐ FAIL ☐	__ + __ + __ = __ PASS ☐ FAIL ☐	__ + __ + __ = __ PASS ☐ FAIL ☐	__ + __ + __ = __ PASS ☐ FAIL ☐
CHECK #4: POST-PEEL SEAL CHECK		__ + __ + __ = __ PASS ☐ FAIL ☐	__ + __ + __ = __ PASS ☐ FAIL ☐	__ + __ + __ = __ PASS ☐ FAIL ☐	__ + __ + __ = __ PASS ☐ FAIL ☐
OVERALL KIT PASS OR FAIL	1 or more check fail = FAIL	PASS ☐ FAIL ☐	PASS ☐ FAIL ☐	PASS ☐ FAIL ☐	PASS ☐ FAIL ☐
COMMENTS:					

2. Tick whether the Check is a pass or fail according to the criteria in the table above
3. If all Checks have passed for each kit then Gavi has passed the User Maintenance Check – go to Section 11.10.
4. If any checks have failed then the User maintenance test has failed and further action is required – see Section 11.9.1

11.9.1. Maintenance Test Failures

If the instrument fails the User Maintenance Test:

1. Record the batch numbers of all consumables used in the test and attach to the completed User Maintenance Test Records.
2. Retain all the consumables that failed in a re-sealable plastic bag, and label the bag with 'Failed User Maintenance Test – Run ID XXXX' where the Run ID is copied from the User Maintenance Test Record. These may be required for further analysis if root cause cannot be found.
3. Retain the failed User Maintenance Test Records.
4. contact your Genea Biomedx representative or authorized local service representative. They will attempt to diagnose the cause of the failure and take corrective actions.

Depending on the type of failure, corrective actions may include:

- Carefully checking consumables for manufacturing defects
- Consultation of the Troubleshooting Guide
- Checking and recalibrating modules or motor axes
- Module or component reinstallation and/or replacement.

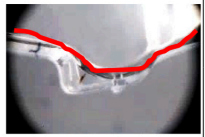
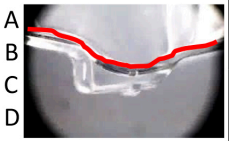
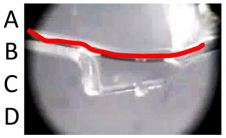
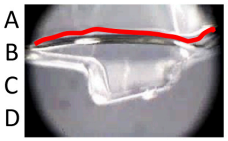
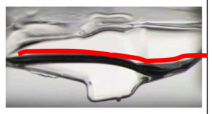
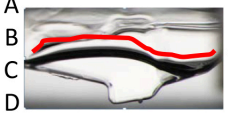
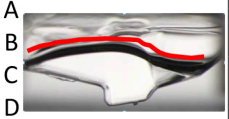
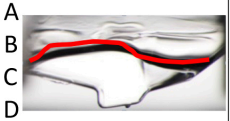
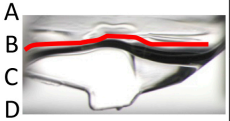
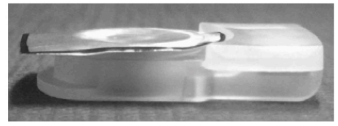
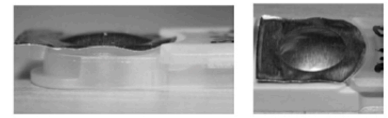
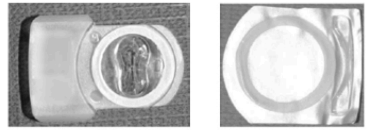
If no resolution can be found to the issue(s) causing Maintenance Test failure, the instrument may have to be returned to the manufacturer.

11.10. Cleanup & Filing

If Gavi passes the User Maintenance Test:

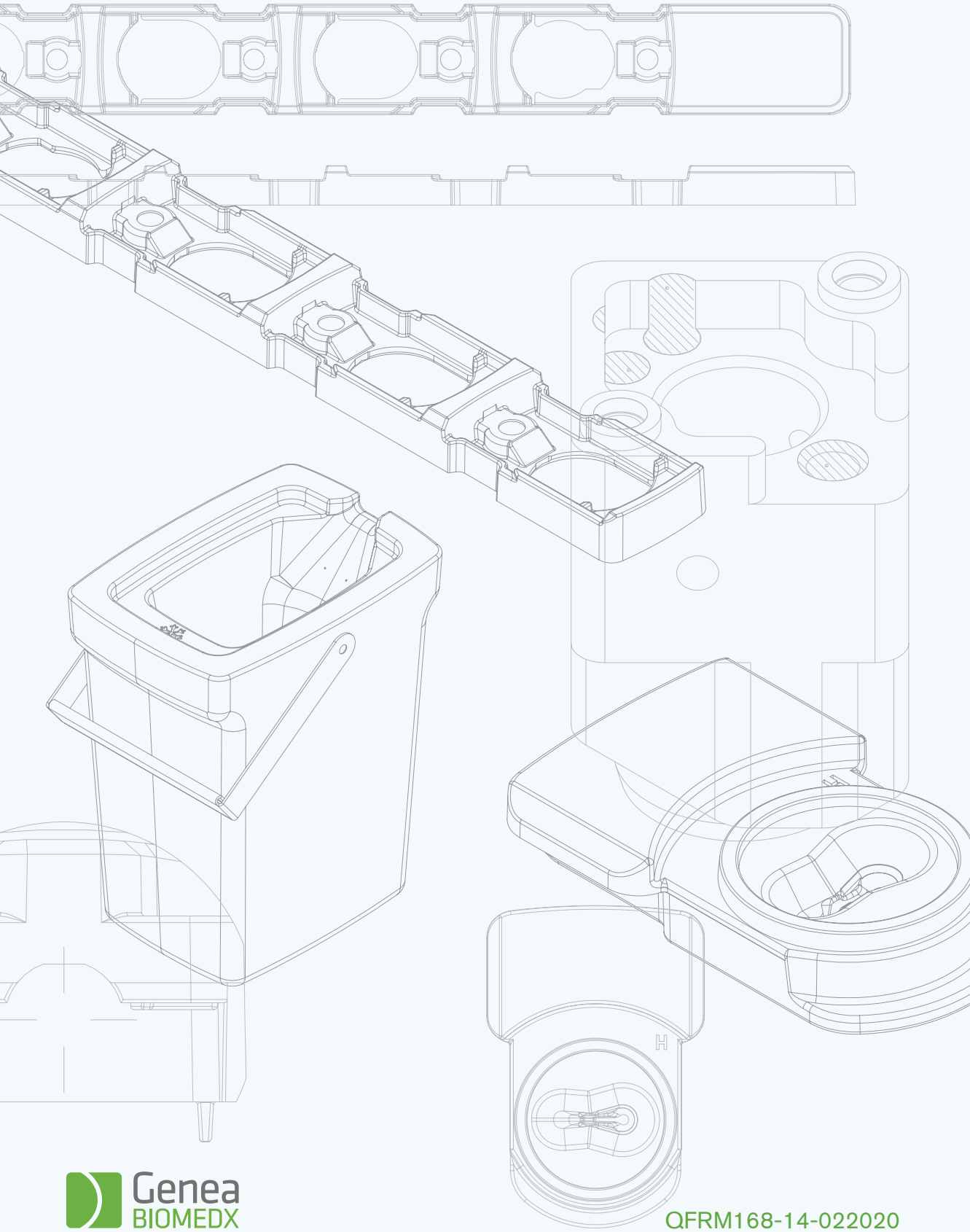
1. Dispose of the used Gavi consumables in accordance with your laboratory's procedures.
2. Retain the completed User Maintenance Test Records for future reference.

11.11. Appendix A: User Maintenance Test Record

Gavi Run ID:	YYYYMMDDHHMMSSGAVI00000			Tester:	INITIALS	
Check #1: Drain Volume Assessment Time:	**Outlier (0.04uL or less)**	**Nominal (0.05uL)**	**Nominal (0.09uL)**	**Nominal (0.22uL)**	**Outlier (0.26uL or more)**	
	☐ A ☐ B ☐ C ☐ D 	☐ A ☐ B ☐ C ☐ D 	☐ A ☐ B ☐ C ☐ D 	☐ A ☐ B ☐ C ☐ D 	☐ A ☐ B ☐ C ☐ D 	
Check #2: Final Volume Assessment Time:	**Outlier (0.5uL or less)**	**Nominal (0.7uL)**	**Nominal (1.0uL)**	**Nominal (1.2uL)**	**Outlier (1.6uL or more)**	
	☐ A ☐ B ☐ C ☐ D 	☐ A ☐ B ☐ C ☐ D 	☐ A ☐ B ☐ C ☐ D 	☐ A ☐ B ☐ C ☐ D 	☐ A ☐ B ☐ C ☐ D 	
Check #3: Pre-Peel Seal Check	**Nominal**			**Outlier**		
	☐ A ☐ B ☐ C ☐ D	No Popping AND Concave/Flat Lid		☐ A ☐ B ☐ C ☐ D	Popping OR Bulging Lid	
Check #4: Post-Peel Seal Check	**Nominal**			**Outlier**		
	☐ A ☐ B ☐ C ☐ D	Complete Seal AND No Water Visible		☐ A ☐ B ☐ C ☐ D	Incomplete Seal OR Water Visible	

12. INDEX

13. NOTES



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