

Parsortix® PR1 WICS System Operating Manual



Product Name: Parsortix PR1 with in-cassette staining
Product Code: PTX-PR1-RUO-B

For Research Use Only. Not for use in diagnostic procedures.



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1. Product Overview

The Parsortix PR1 with in-cassette staining (hereafter referred to as “the Parsortix instrument”) is a laboratory benchtop instrument that facilitates the separation and capture of cells present in blood based on their size and deformability.

When the instrument is used together with the Parsortix cell separation cassette and other specific consumables and reagents, this combination is known as the Parsortix PR1 with in-cassette staining system (hereafter referred to as “the Parsortix system”).

The Parsortix cell separation cassette is a single use, non-sterile, precisely manufactured slide containing an enclosed separation structure which preferentially captures rare/target cells as the sample passes across a series of steps.



Warning: The Parsortix system is for RESEARCH USE ONLY and not for use in diagnostic procedures.



Warning: The Parsortix system is intended for use by trained laboratory personnel.



Warning: It is essential to read the Health and Safety Information presented in section 5 before assembling or operating the Parsortix instrument.

2. Materials Provided

- 1 x Parsortix instrument pre-loaded with application software and core protocol files: CTC01, PX2_PF, PX2_S99F, PX2_preH, PX2_H, PX2_CT, PX2_C, PX2_F, PX2_Maintenance, PX2_LOAD, PX2_Stain1, PX2_Stain2, PX2_Stain3, PX2_Stain4
- 2 x Non-slip pads
- 1 x Drip tray
- 1 x Flushnut tool
- 1 x Manual flush kit
- 1 x 500 mL Glass bottle, 1 x 250 mL glass bottle, 6 x 15 mL plastic tubes, 4 x 50 mL plastic tubes, all with corresponding lid assemblies
- 1 x 50 mL Tube rack
- 1 x Separation cassette clamp
- 4 x Sets of replacement O-rings for sample mount
- 2 x Sets of replacement filters for the reagent and waste reservoir lid assemblies
- 1 x External main voltage power supply (110V/240V automatically adjustable) and leads
- 1 x Operating Manual (printed)



Warning:

Risk of eye damage. This equipment has several sections of flexible plastic tubing that are not fixed. Handle with care to avoid tubing or an aerosol striking the eyes.



Important:

The instrument sample mount is designed only for the specified tube brand and parts (see list below). Other tubes may not fit correctly or may damage the sample mount O-ring seals.

3. Materials Required but not Provided

3.1 Blood Sample Tubes

The following blood collection tubes (BCTs) may be used to **collect** blood samples for processing by the Parsortix system:

- 10 mL BD Vacutainer K₂EDTA Tubes (BD catalogue #366643 [USA], 367525 [EU])
- Streck Cell free DNA BCT (Streck catalogue #218996)
- PAXgene Blood ccfDNA Tube (BD Biosciences catalogue #768165)
- CellSave Preservative Tubes (Menarini catalogue #7900005)
- Roche Cell-Free DNA Collection Tube (Roche catalogue #7785666001)
- Cell3™ Preserver blood collection tubes (Nonacus catalogue #PRE_C3P_WBS_50)
- TransFix/ K₂EDTA 9mL Vacuum Blood Collection Tubes (Cytomark catalogue #TVT-09-50)

Only the following sample tubes may be used to **load** samples onto the Parsortix system. If blood has been collected in an alternative BCT it **must** be transferred to a compatible tube prior to sample processing. See section 7.7 for additional details.

- 10 mL BD Vacutainer K₂EDTA tubes (BD catalogue #366643 [USA], 367525 [EU])
- 12 mL Polystyrene urinalysis tube (SLS catalogue #G160101)
- 50 mL Falcon tube (BD or Corning catalogue #352070)



Warning:

Use of alternative sample tubes may cause damage to the sample mount or present a health and safety risk (e.g. glass tubes may break).

3.2 Consumables and Reagents

- Parsortix GEN3P 6.5 Cell Separation Cassette (ANGLE catalogue #CAS-3P-RUO-65)
- Parsortix GEN3C Cleaning Cassette (ANGLE catalogue #CAS-3C-RUO-CC)
- 1× Phosphate-Buffered Saline (PBS) without Ca⁺ & Mg⁺ (Corning catalogue #21-040-CM, or equivalent)
- Absolute Ethanol (99.8+%) (Fisher Scientific catalogue #10342652, or equivalent)
- Cleaning reagent, choose from:
 - Prokrenz 120 (Steris catalogue #143205WR)
 - Decon Decomatic (Fisher Scientific catalogue #1173118)
- Waste reagent, choose from:
 - Prokrenz 120 (Steris catalogue #143205WR)
 - Decon Decomatic (Fisher Scientific catalogue #1173118)

Materials required but not provided should be used and handled according to the relevant manufacturer's instructions.

4. Technical Specifications

Supply voltage: 110V/240V automatically adjustable AC, 50/60Hz input

Instrument input voltage: 24V DC

Instrument current rating: 3.15A

Instrument input fuse rating: 3.15 A Fast 20 mm



Warning:

Only replace the input fuse with the parts specified:

Suitable input fuse ratings are F3.15AL250V or F3.15AH250V

L denotes a Low breaking capacity Cooper Bussmann S500 Series part

H denotes High breaking capacity Littelfuse 216 Series part

The Parsortix instrument has been tested in accordance with the following electrical safety standards:

- IEC 61010-1:2010 +AMD1:2016; IEC 61010-2-081:2019;
- EN 61010-1:2010 +A1:2019; EN 61010-2-081:2020;
- UL 61010-1:2012/R:2019-07; UL 61010-2-081:2019;
- CSA C22.2 No 61010-1:2012/A1:2018-11; CSA C22.2 No 61010-2-081:19

5. Storage and Handling

5.1 Positioning and interference

The Parsortix instrument is for indoor use only and must be stored and operated according to the following environmental conditions:

Operation: 18°C to 25°C / 64°F to 77°F at 95 – 105 kPA. Maximum operating altitude 2000m.

Storage: 0°C to 40°C / 32°F to 104°F at 95 – 105 kPA.

Humidity: 20% - 80% R.H.

The Parsortix instrument complies with the emission and immunity requirements described in the IEC 61326 standard as set out in the Declaration of Conformity supplied with the instrument. This device complies with Part 15 of the FCC Rules.

Operation is subject to the condition that this device does not cause harmful interference, and this device must accept any interference received, including interference that may cause undesired operation.

The Parsortix instrument must not be used near sources of strong electromagnetic radiation (e.g. unshielded intentional RF sources), as these can interfere with the proper operation.

The Parsortix instrument should not be placed on the same bench as a centrifuge to minimise vibration.

The Parsortix instrument must be positioned to allow easy user access to the mains power input connection and rear instrument panel power input socket. Both connection points may be used as a means of disconnecting the instrument from its power source.



Warning:

The protection provided by the equipment may be impaired if the equipment is used in a manner other than that specified in these instructions.

- Total shipping carton dry weight, including the Parsortix instrument and accessories described: 19 kg (42 pounds)
- Shipping box dimensions (length x width x height): 58 cm (22.5 inches) x 50 cm (19 inch) x 50 cm (19 inch)
- Parsortix instrument dimensions (length x width x height): 46 cm (18 inch) x 36 cm (14 inch) x 28 cm (11 inch)
- Bench space required (length x width x height): 80 cm (30 inch) x 50 cm (20 inch) x 50 cm (20 inch)
- Parsortix instrument power requirement is 1x outlet, 110V-240V (see Section 4 for details).

5.2 Potential Hazards

The Parsortix instrument is designed for use in a biomedical research laboratory. It must be:

- Situated and operated only in facilities with the specialised infrastructure and general equipment required for biomedical research or clinical laboratory activities.
- Operated by personnel trained in biomedical research laboratory operations, including equipment and materials required to perform laboratory tasks correctly and safely.
- Used in association with and within existing health and safety regulations for the correct and safe use of the specific reagents being used for the operation of the Parsortix instrument.

Operating the Parsortix instrument involves two main potential hazards for the user, as detailed in Table 1.

Hazard	Description	Action to minimise risk
Biohazards 	Handling blood that may carry bloodborne pathogens	During sample handling: establish appropriate operating procedures, use containment and personal protective equipment (PPE) and consider vaccinations. During equipment operation: Carefully mount and remove sample tubes and wear PPE. Clean spillages as described in this section. Handling of waste: ensure that the waste reservoir is prepared as instructed in Section 7.5.1 and that waste material is handled and disposed of appropriately. Wear PPE.
Chemical hazard 	Exposure to chemicals that may be caustic, noxious, toxic, volatile or flammable	Establish operational procedures and risk- assessment: store, handle, deploy, and disposal of chemical reagents in accordance with the control of substances hazardous for health (COSHH) instructions of each reagent. Wear PPE.

Table 1. Two main hazards associated with the operation of the Parsortix instrument.

The Parsortix instrument has been designed to minimise the risk of inadvertent exposure to blood. This includes a closed flow path from the sample to the waste reservoir. Always prefill the waste reservoir with 50 mL Decon Decomatic or Proklenz 120 before operating the system.

Blood spillage may occur during mounting and/or removal of a blood tube and separation cassette, presenting a risk of exposure from residue on an instrument component. The following actions will reduce the risk of exposure whilst operating the Parsortix system:

- Follow the instructions for mounting and removing sample tubes (Section 8.2).
- Wearing PPE including eye protection.

- In case of a leak during operation (e.g. in the cassette clamp), or if biohazardous material is accidentally spilled on the instrument, immediately wipe with a tissue pre-soaked with the approved detergents (Section 3), then wipe the area again with a 70% Ethanol wipe.
- In the case of a large spillage, HSE regulation (OCE23) for blood spillage suggests the use of chlorine-releasing disinfectant (e.g. sodium hypochlorite solution, min of 10000 par/million, freshly prepared). Otherwise follow the local health and safety regulations for blood and chemical spillage.

Hazardous chemical storage, handling, spillage, or waste disposal must be managed according with the COSHH of each reagent and the laboratory health and safety and environmental regulations.

6. Assembly and Installation

6.1 Key Components of the Parsortix Instrument

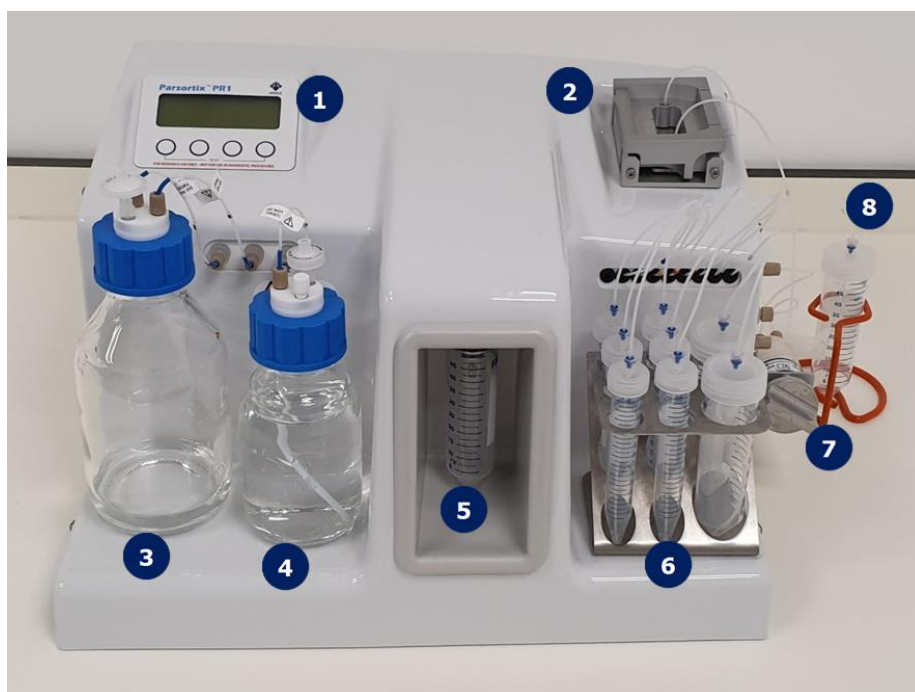


Figure 1. Key components of the Parsortix instrument.

- | | |
|-----------------------------|---|
| 1. Screen and control panel | 5. Sample mount with drip tray |
| 2. Cassette clamp | 6. Priming, cleaning, and reagent lines |
| 3. 500 mL waste reservoir | 7. Harvest valve |
| 4. 250 mL buffer reservoir | 8. Harvest line with harvest waste tube |

6.2 Unpacking the Box

Carefully follow the instructions in this section to assemble and install the Parsortix instrument.

- Remove all the components from the shipping carton and verify that all the items in the enclosed contents list are present and not damaged. Contact ANGLE support (see section 11) in case of damaged items. Do not dispose of the packaging; please store the box in case the instrument needs to be transported in the future.

Note: Some components (e.g. spare parts) may not be required immediately and should be stored safely for future use.

- Place the instrument in the selected final location on the benchtop.

Important: Once assembled, do not move the instrument while the reagent bottles and tubes are connected as these are not held securely in place and may fall and break.

6.3 Attaching the Drip Tray

- The drip tray helps contain any spillages or leaks in the sample mount area. Attach the drip tray over the sample mount as shown in Figure 2. It is held in place by a magnetic catch.



Figure 2. Positioning the drip tray.

6.4 Applying Non-Slip Pads

- Attach the non-slip pads onto the surface of the bottle bays on the left (large pad) and right (small pad) on the Parsortix PR1 instrument. After identifying the correct position, peel the backing paper from the pads and apply them by hand (Figure 3).

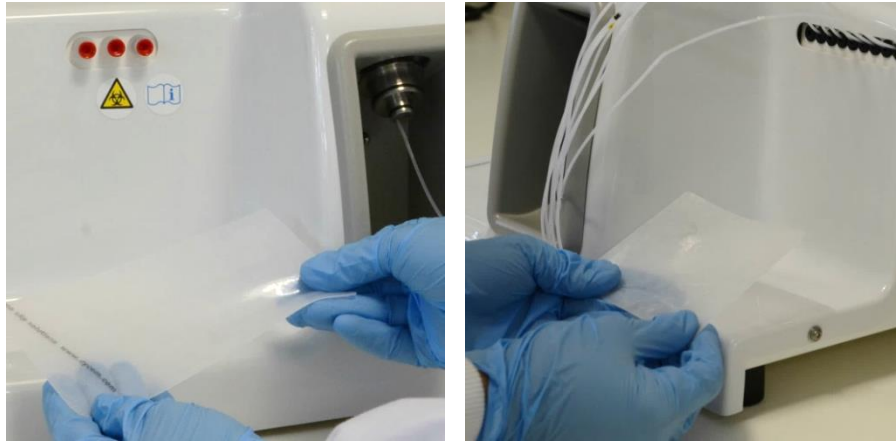


Figure 3. Placing the non-slip pads on the Parsortix instrument.

6.5 Connecting the Cassette Clamp

The clamp is the metal case that securely holds the separation cassette during the operation of the Parsortix instrument. It is supplied with connection tubes already attached. The inlet and outlet tubes are labelled “I” and “O” respectively. The cassette clamp connects to the back of the harvest valve mounted on the right side of the instrument (Figures 4 and 5).

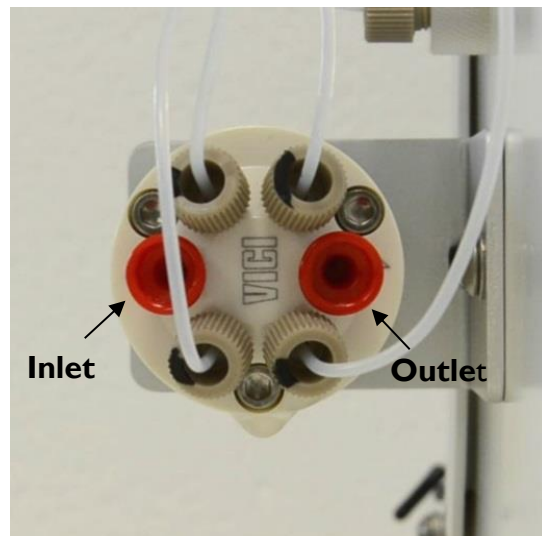


Figure 4. Cassette clamp (1) connected to the harvest valve (2). Figure 5. Rear view of the harvest valve.

- To connect the clamp, carefully remove the red protection covers on the two unused ports at the back of the harvest valve and connect each line to the correct port according to in Table 2.

Line	Port number	Position (as viewed from rear of valve)
Inlet "I"	1	Left
Outlet "O"	4	Right

Table 2. Identification of connection ports in the harvest valve.

6.6 Connecting Waste and Buffer Reservoirs

- The waste and reagent reservoirs are provided with caps pre-fitted with tubing, connectors, and PTFE filters. Identify each reservoir bottle and attach the corresponding cap (Figure 6).
- Connect the tubing on each reservoir cap to the Parsortix instrument as detailed below (Figure 6a and 6b):

Waste reservoir: Carefully remove the red protection cap from the **left and middle connection port** on the **left-hand** front of the instrument. Manually screw the plastic tubing connectors into the holes. Place the bottle on the **left** of the bottle bay.

Buffer reservoir: Carefully remove the red protection cap from the **right connection port** on the **left-hand** front of the instrument. Manually screw the plastic tubing connector into the hole. Place the bottle on the right of the bottle bay.



Figure 6a. Connecting the waste reservoir.



Figure 6b. Connecting the buffer reservoir.

6.7 Connecting the Reagent Tubes

The reagent tubes hold the fluids required for priming and cleaning the system, as well as the reagents for in-cassette staining. The cluster of tubing lines emerging from the right-hand front of the instrument enables the system to take up the reagents. The lines are tagged with a coloured label according to the diagram in Figure 7. The lines connect to 15 mL (x6) or 50 mL (x2) plastic tubes held in an 8-space metal rack placed on the right-hand front bay.

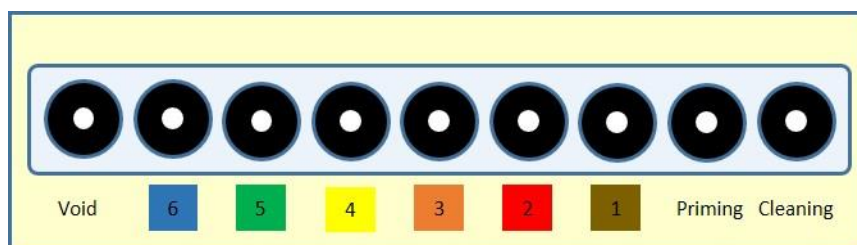


Figure 7. Reagent line identification labels.

- To connect the lines, remove the end cap from the line and carefully slide it through the luer cap of a tube (Figure 8). A small amount of force might be necessary but take care not to kink the line. The line should reach just short of the bottom of the tube when the cap is screwed on. Use Table 3 to match the lines with the correct reagent tube. Once the line is connected, place the tube in the 8-space metal rack.



Figure 8. Connection of lines to reagent tubes.

Line	Quantity	Tube Size	Use
1-6 (coloured)	6	15 mL	Staining reagents
P	1	50 mL	Priming fluid
C	1	50 mL	Cleaning fluid

Table 3. Identification of reagent tubes and lines.

6.8 Connecting the Harvest Waste Tube

Waste fluid produced during cleaning is collected in a 50 mL Falcon tube held in a rack behind the harvest valve.

- The harvest valve has an attached line with a free end; remove the black end cap and carefully slide it through the luer cap of a 50 mL Falcon tube (Figure 9). Place the tube in the tube rack.



Figure 9. Connection of the harvest waste line to the waste tube.

6.9 Starting the Parsortix Instrument

- Connect the power cord to the Parsortix instrument and to a mains outlet.
- Turn on the instrument using the power switch on the left side panel (Figure 10). The internal components will be heard moving as the start-up sequence takes place. The display screen will report the progress before presenting the main menu with the instruction [Select Protocol] (Figure 11).
- Now the instrument has successfully turned on and is ready for use.



Warning:

Do not connect external equipment to the instrument. The sockets on the left-hand side are for the manufacturer's use only.

6.10 Before First Use

After assembly and before the first use, a new cleaning cassette needs to be prepared and the Parsortix instrument must undergo two full cleaning processes to clean, flush out any air, and prime the instrument. See section 8.3.5 for details of how to perform the cleaning process.

7. Instrument Operating Procedures



Warning:

Before the first use, the Parsortix instrument must be assembled and installed as detailed in Section 6.

7.1 Instrument Start-Up

The Parsortix instrument is turned on and off using the power switch on the left side panel (Figure 10). The internal components will be heard moving as the start-up sequence takes place.



Figure 10. Side panel showing the power switch.

7.2 User Interface Screen and Keypad

The user interface screen (Figure 11) displays information about the system status and prompts for user input. The four buttons on the keypad below the user interface screen are soft keys that, when pressed, trigger the functions displayed on the screen above each button.

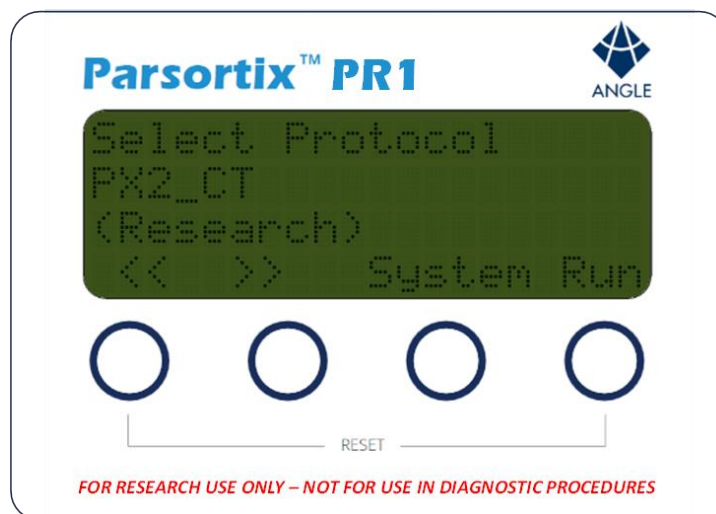


Figure 11. Parsortix instrument user interface screen and keypad.

- The main menu allows access to the protocols installed on the instrument. Press the left [<<] and right [>>] keys to scroll to browse the protocols, then press [Run] to activate the required protocol.
- When the instrument is running, one soft key will be allocated an [Abort] function. Pressing and holding [Abort] will stop the instrument running and return the user to the main menu. **[Abort] should only be pressed when instructed by ANGLE support. Following an [Abort] action, the Standard Recovery Procedure described in Section 10.1 must be performed.**
- When the instrument is processing a blood sample, one additional soft key will be allocated a [Skip] function. Pressing [Skip] three times will progress the blood processing step to the buffer rinsing step. **[Skip] should only be pressed if the blood processing step has been ongoing for more than 4 hours and the instrument is assumed to be stalled.**
- The [System] key is used for instrument servicing and in consultation with ANGLE Technical Support. It should **not** be operated during normal use. If the [System] key is activated by mistake the screen will show three controls: [USB], [Shutdown] and [Exit]. Press [Exit] to return to the main menu.

7.3 Cleaning Solution Preparation

The cleaning solution used on the Parsortix instrument is either 10% v/v ProKlenz 120 or 10% v/v Decon Decomatic. Use caution and wear appropriate PPE when handling the cleaning solutions.

- Dispense 900 mL deionised water into an empty 1 L (1000 mL) Duran-type bottle or another appropriate container. Alternatively, remove 100 mL of deionised water from a new 1 L (1000 mL) deionised water container.
- Using a sterile 100 mL serological pipette and a pipette aid, aspirate 100 mL of ProKlenz 120 or Decon Decomatic from its original container.
- Dispense the 100 mL of ProKlenz 120 or Decon Decomatic into the 900 mL of deionised water.
- Secure the lid on the bottle / container and invert three times to mix.

- Label the bottle with the contents (e.g., 10% ProKlenz or 10% Decomatic) and an expiry date (2 weeks from the current date).

Note: 10% ProKlenz / 10% Decon Decomatic cleaning solution can be stored at room temperature for up to 2 weeks after preparation. After 2 weeks, any unused cleaning solution must be disposed of appropriately.

7.4 Use of Parsortix Cassettes

7.4.1 Types of Parsortix Cassettes

Two types of Parsortix cassette are required for the operation of the Parsortix system.

- The Parsortix GEN3P 6.5 Cell Separation Cassette (ANGLE catalogue #CAS-3P-RUO-65) for processing blood samples (Figure 12a). This cassette is single use.
- The Parsortix GEN3C Cleaning Cassette (ANGLE catalogue #CAS-3C-RUO-CC) for instrument cleaning only (Figure 12b). This cassette may be re-used for up to one week.

Both types of cassettes are supplied as consumables by ANGLE.



Figure 12a. Parsortix GEN3P 6.5 Cell Separation Cassette



Figure 12b. Parsortix GEN3C Cleaning Cassette



Warning:

Parsortix cassettes are fragile and must be handled with care. ALWAYS handle the cassette by the edges and avoid applying pressure to its surfaces. Ensure no cracks or damages are visible on the cassettes before using them.

7.4.2 Cassette Removal and Loading

Note: When handling the cassette clamp, position your body in front of the instrument and lean towards the instrument. This will limit the distance you can pull the clamp towards yourself and help prevent damaging the lines. Before use, check the condition of the tubing and do not use if damaged. Report damaged tubing to your local ANGLE technical support provider.



Warning:

Do not bend, kink, or pull on the tubing connecting the cassette clamp to the instrument.

To load or change a cassette:

- Ensure the clamp is positioned on top of the instrument (Figure 13a).
- Open the latch on the left-hand side of the clamp (Figure 13b).
- Hold the clamp tightly and lift it off the instrument. Carefully turn it over so the tubing attached to the top of the clamp is now facing towards the instrument.

Note: Take care when handling the clamp not to pull or twist the inlet or outlet lines.

- Carefully open the clamp (Figure 13c).



Figure 13a. Positioning the clamp



Figure 13b. Opening the latch



Figure 13c. Rotating and opening the clamp

- Remove the cassette from inside the clamp (if present) and retain or dispose of as appropriate.
- Choose an appropriate new cassette type and remove it from the package.
- Hold the cassette vertically so that the open notch is in the upper left-hand corner (Figure 14).



Figure 14. Parsortix cassette in correct orientation for loading into the clamp.

- Position the new cassette so that the notch in the top-left corner of the cassette connects with the peg in the top left corner of the clamp (Figure 15a).
- Ensure that the lower left-hand corner of the cassette also engages with the corresponding peg in the clamp (Figure 15b).



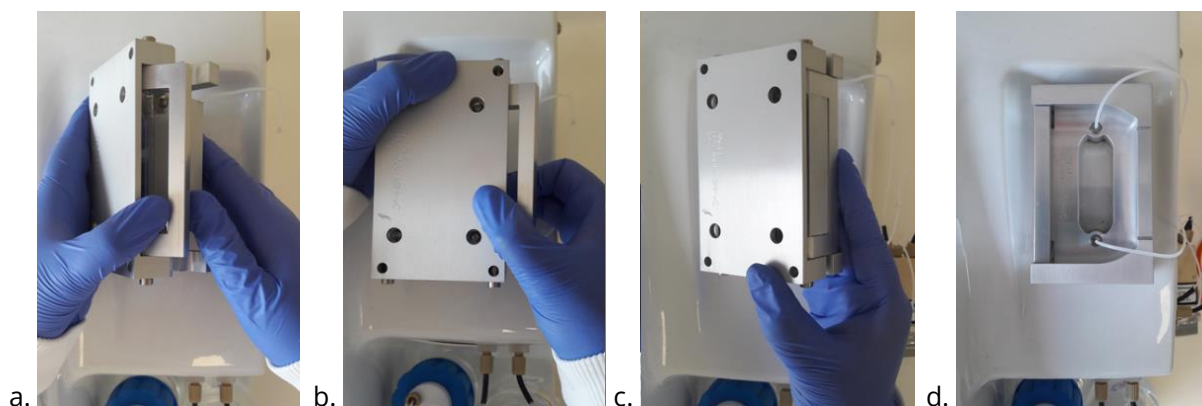
Figure 15a. Loading a Parsortix cassette into the clamp.



Figure 15b. Aligning the bottom peg.

- Close the left-hand side of the clamp over the cassette, making sure the cassette remains in place and secure the latch (Figure 16 a – c).
- Flip the clamp back over so that the cassette is visible through the window and the tubing connected to the clamp is facing upward, away from the instrument (Figure 16d).

Note: Take care when handling the clamp not to pull or twist the inlet or outlet lines.



Figures 16a - d. Securing the cassette clamp into position.



Warning: All used cassettes should be handled and disposed of as a biohazard.



Warning: Risk of blood aerosol. Never attempt to remove a cassette from its clamp whilst instrument is in operation.

7.5 Reagent and Waste Reservoirs

Details of each reservoir bottle, its position on the Parsortix instrument, and the **required reagents before beginning any operation** are in Table 4.

Reservoir	Bottle Volume (mL)	Line ID	Position on Instrument	Connection Port(s)	Required Reagent	Refill at (mL)	Refill to (mL)
Waste	500	W	Left bay	Left and middle	Undiluted Decon Decomatic, or undiluted ProKlenz 120	N/A: Replace at ≥ 400	50 cleaning reagent
Buffer	250	B	Left bay	Right	PBS buffer without Ca/Mg	≤ 100	250
Priming	50	P	Right bay	Second from Right	Absolute Ethanol	≤ 10	50
Cleaning	50	C	Right bay	Right	10% ProKlenz 120 or 10% Decon Decomatic	≤ 20	50

Table 4. Parsortix instrument reagent and waste bottle identification and set up.

At the start of the sample processing protocol, the software will prompt the user to confirm each reservoir is setup correctly.

The waste reservoir, the buffer reservoir and the cleaning reservoir bottles should be removed and replaced as part of the weekly maintenance.

Note: When removing and replacing the bottles, it is important to firmly hold the lid with one hand and rotate the bottle with the other hand. Holding the lid stationary will prevent kinking of the tubing connected to the lid.

7.5.1 Waste Reservoir

The waste reservoir bottle should be removed and replaced with an empty bottle whenever the volume of liquid inside is ≥ 400 mL, and during the weekly maintenance.

- Remove the waste reservoir bottle by firmly holding the lid with one hand and use the other hand to rotate the bottle in a clockwise direction.
- Appropriately dispose of the contents and place the bottle aside for cleaning.
- Wipe the tubing lines attached to the lid with an alcohol-soaked wipe.
- Add 50 mL of undiluted Decon Decomatic or Prokrenz 120 to a new, clean, 500 mL Duran-type bottle.
- Firmly hold the waste reservoir lid and carefully screw the new waste reservoir bottle onto the lid by rotating the bottle in a counterclockwise direction.

7.5.2 Buffer Reservoir

The buffer reservoir should be removed and refilled when the volume of liquid inside is ≤ 100 mL and replaced as part of the weekly maintenance.

- Remove the reservoir bottle by firmly holding the lid with one hand and use the other hand to rotate the bottle in a clockwise direction.
- Wipe the line attached to the lid with an alcohol-soaked wipe.
- To refill, add the appropriate volume of PBS buffer to the bottle (see Table 4 for details).
- To replace, obtain a clean 250 mL Duran type bottle and fill with 250 mL of PBS buffer.
- Firmly hold the reservoir lid and carefully screw the newly filled reservoir bottle onto the lid by rotating the bottle in a counterclockwise direction.
- Run the PX2_LOAD protocol to remove any air potentially introduced by the removal of the lid from the buffer reservoir bottle (see Section 8.3.6 for details).

7.5.3 Priming and Cleaning Reservoirs

The priming and cleaning reservoirs should be refilled when the volume contained is lower than the requirement in Table 4. Furthermore, the cleaning reservoir should be replaced as part of the weekly maintenance.

- Remove the reservoir (plastic tube) by firmly holding the lid with one hand and use the other hand to rotate the tube in a clockwise direction.
- Wipe the line attached to the lid with an alcohol-soaked wipe.
- To refill, add the appropriate volume of reagent to the plastic tube (see Table 4 for details).
- To replace, obtain a clean 50 mL plastic tube and fill with the appropriate volume of reagent (see Table 4 for details).
- Firmly hold the tube lid and carefully screw the newly filled reservoir tube onto the lid by rotating the tube in a counterclockwise direction.

7.6 Harvest Valve Operation

During operation of the Parsortix instrument, the harvest valve must be manually rotated between two set positions: "SEP" and "HAR".

- The default position for the valve is "SEP", indicating "separation" (Figure 17).
- The valve must remain in the "SEP" position for all protocols unless otherwise instructed.



Figure 17. Harvest Valve in separation "SEP" position.

- The alternative position is "HAR", indicating "harvest" (Figure 18).
- "HAR" should only be used when prompted by the instrument at specific points during the execution of the **PX2_H** protocol.



Figure 18. Harvest Valve in the harvest "HAR" position.

7.7 Collecting and Handling Blood Samples

Blood may be collected in a range of collection tubes, but must only be processed on the Parsortix system in one of three specified tube types; see Section 3 for additional details.

7.7.1 K₂EDTA Tubes

- Blood samples should be stored at room temperature, protected from direct sunlight, and may be used with the Parsortix system for up to 48 hours post-draw.
- Invert the blood tube 5 times before processing.

7.7.2 50 mL Falcon Tubes

- Suitable for higher sample volumes (between 2.5 mL and 30 mL)
- Different 50 mL tube brands must have the same dimension specifications of a Corning Falcon 50 mL tube to ensure they fit correctly and avoid damaging the O-ring seal.

7.7.3 12 mL Polystyrene Urinalysis Tube

- Suitable for lower sample volumes (between 1 mL and 10 mL)

Note: After transferring the sample to one of the compatible tubes, rinse the original BCT with 1 mL of PBS without Ca/Mg and add the rinse to the new tube.

Note: Blood samples collected in Streck Cell-Free DNA BCTs may be used with the Parsortix system for between 72 hours and 120 hours post-draw.

Note: To avoid spillages, blood tubes should not be filled beyond 80% of their total volume.



Warning:

Risk of blood aerosol. Never attempt to remove a vacutainer from its mount while instrument is in operation.



Warning:

Blood preservative tubes containing Sodium Heparin **must not** be used with the Parsortix instrument.

7.8 Process Workflow and System Protocols

The operation of the Parsortix system is divided into distinct processes controlled by software-based protocols. Two general choices are available: blood sample processing without in-cassette staining using the CTC01 combined protocol, or blood processing with in-cassette staining using separate protocols in individual steps.

- The sample processing workflow is summarised in Figure 19:

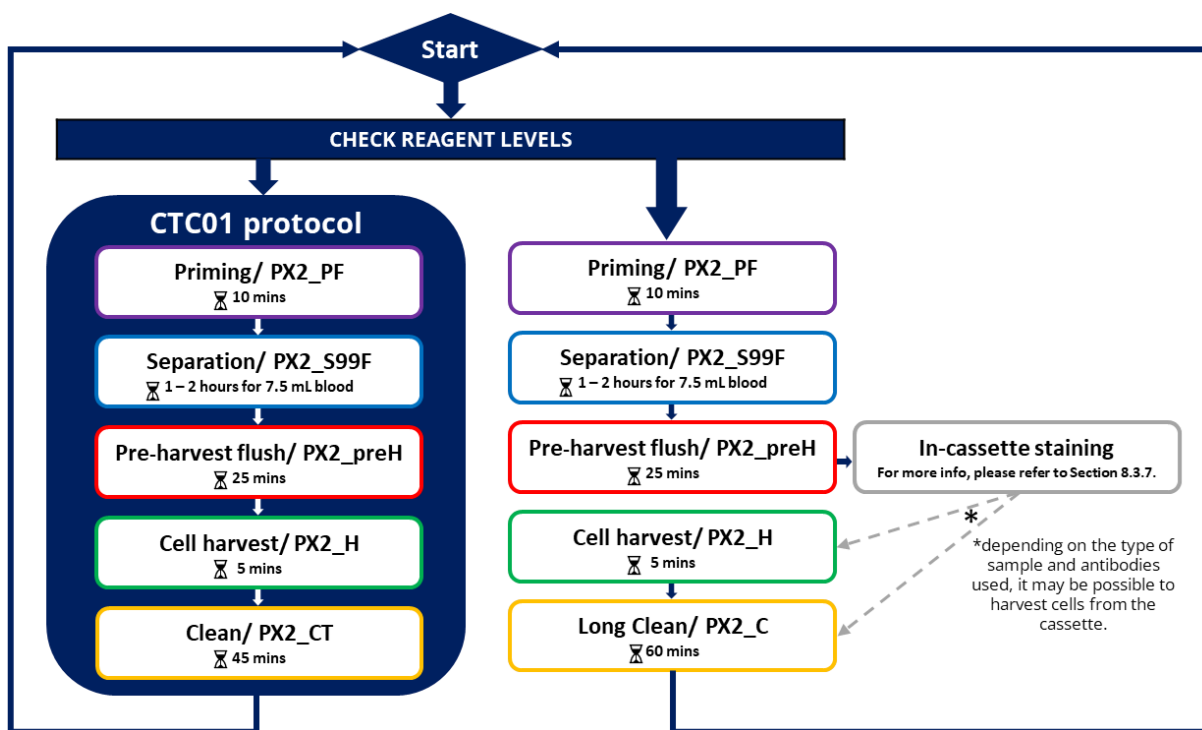


Figure 19. Summary of the sample processing workflow.

- The pre-installed software-based protocols are detailed in Table 5.

Process	Protocol name	Description	Time
Complete sample processing	CTC01	The complete protocol for sample processing that includes priming, separation, pre-harvest flush, cell harvest and clean. Not for use with in-cassette staining.	Up to 3.5 hours for a 7.5 mL blood sample
Priming	PX2_PF	Prepares the instrument to receive a blood sample by filling the onboard Parsortix cell separation cassette with buffer solution.	10 mins
Separation	PX2_S99F	Requests a new blood sample which is then separated through the cassette using 99mbar pressure.	1 – 2 hours for a 7.5 mL blood sample
Pre-harvest flush	PX2_preH	Flushes the instrument to remove residual blood cells prior to harvesting the captured cells.	25 mins
Cell harvest	PX2_H	Releases cells captured in the cassette for collection into a collection tube via the harvest line.	5 mins
In-cassette staining	PX2_Stain1, PX2_Stain2, PX2_Stain3, PX2_Stain4	Immunofluorescence staining of captured cells.	Please contact your local application support team for further information
Short clean	PX2_CT	Cleans and resets the instrument.	45 mins
Full clean	PX2_C	Cleans and resets the instrument, including the staining reagent lines.	60 mins
Maintenance	PX2_Maintenance	A protocol for the routine maintenance that includes two runs of buffer replacement, priming and clean.	~75 mins
Buffer replacement	PX2_LOAD	Removes any air potentially introduced by replacing / refilling the buffer reservoir.	10 mins

Table 5. Parsortix protocols pre-installed on the instrument.

8. Routine Operation

8.1 Initial Checklist

Always perform the following steps before operating the Parsortix system to maintain cleanliness and minimise the risk of cross contamination between samples:

- Visually inspect the instrument for any signs of kinks, leaks, or damage.
- Ensure an empty clean 50 mL Falcon tube is attached to the sample mount.
- Ensure the harvest waste line “H” is plugged into the cap of the harvest waste tube.

- Ensure the harvest waste tube (50 mL Falcon tube) attached to the harvest line is empty. If not, discard the tube, wipe the harvest line with an alcohol wipe, and attach a clean and empty 50 mL Falcon tube.
- Ensure a cleaning cassette is inside the clamp.
- Ensure the harvest valve is turned clockwise to the "SEP" position.
- Ensure the reagent reservoir tubes 1-6 are empty and the lines are clean.
- Check the level of the waste and reagents to ensure that the reservoirs are filled appropriately. See Section 7.5 for details of the waste and reagent requirements.
- If the Parsortix instrument was not cleaned after the last operation or within the last 24 hours, perform the cleaning protocol as described in Section 8.3.5.

8.2 Routine Sample Processing

After completing the initial checklist (section 8.1):

- In the main menu screen, select the protocol CTC01 using the scroll arrows and press [Run] then [Start].
- At prompt "check Buffer", confirm that sufficient buffer is in the buffer reservoir bottle and press [OK].
- At prompt "check Cleaning rgt", confirm that sufficient cleaning reagent is in the cleaning reservoir bottle and press [OK].
- At prompt "check Priming rgt", confirm that sufficient Ethanol is in the priming reservoir bottle and press [OK].
- At prompt "Waste empty?", confirm that the waste reservoir bottle is less than 400 mL full and press [OK].

Note: See section 7.5 for details of waste and buffer reservoir requirements.

- At prompt "Insert New Cassette" "Ready?", insert a new Parsortix GEN3P 6.5 cell separation cassette as described in Section 7.4.2. and press [OK] to continue.
- At prompt "Rinse Vacutainer" "Start?":
 - Detach the 50 mL Falcon tube (left in place after the previous cleaning protocol) from the sample mount keeping the line inside the tube.
 - Press [OK] to start the rinse and collect the rinse fluid inside the Falcon tube.
 - Fully remove the Falcon tube, taking care not to flick fluid off the tip of the line.
- At prompt "Preparing Sample" "Attach Vacutainer...":
 - Invert the blood sample tube five times to fully re-suspend the blood cells, then immediately attach it to the sample mount with the sample line inside the tube. A twisting action will help to push the sample tube over the O-ring and into position.



Warning:

Take care when mounting the vacutainer to ensure the O-ring is not forced out of place or becomes distorted.

- Push the sample tube towards the instrument, securing it in the vertical position (Figure 20) and press [OK].

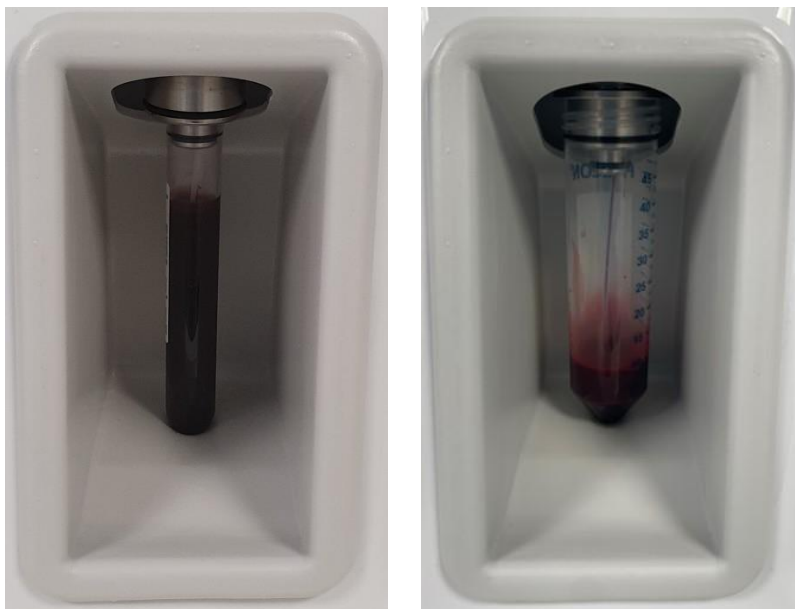


Figure 20. Blood sample in secure vertical position (left: in EDTA vacutainer, right: in 50 mL Falcon tube)

- At prompt "Preparing Sample" "Start?", press [OK] to start the separation. This process takes approximately 1-2 hours for a 7.5 mL blood sample.
- After approximately 30 minutes, pull the sample tube from its vertical position without disconnecting it from the instrument and re-suspend any settled blood cells by tapping the bottom of the same tube (Figure 21).



Figure 21. Re-suspending the settled blood cells by tapping the sample tube (left: EDTA vacutainer, right: 50 mL Falcon tube).

- Re-secure the sample tube by pushing it into the vertical position.
- Repeat the resuspension step every 30 minutes during processing.

The system will automatically stop once all the sample has been processed. Captured cells may now be harvested from the cell separation cassette.

- At prompt "Rotate Valve..." "Anticlockwise", rotate the harvest valve counterclockwise to the position "HAR" (as shown in Figure 18) and press [OK].
- At prompt "Harvest" "Start?" :
 - Remove the harvest line from the harvest waste tube and clean it with an alcohol-soaked wipe.
 - Place the tip of the harvest line into a collection vessel (e.g. an Eppendorf tube).
 - Press [OK] to start the harvest. A total volume of 210 μ L will flow through the harvest line in several pulses. This contains the captured cells, for use in downstream analysis.
- Place the harvest line back in the harvest waste tube.
- At prompt "Rotate Valve..." "Clockwise", rotate the harvest valve clockwise to the position "SEP" and press [OK].
- At prompt "End of Harvest" "Insert Cleaning Cass.", insert a Parsortix GEN3C cleaning cassette as described in Section 7.4.2.
- Press [OK] to continue. The instrument will now clean itself for around 45 minutes.

- At prompt "Remove Vacutainer", remove and discard the current sample tube then press [OK].
- At prompt "Clean Vacutainer-line", use an alcohol-soaked wipe to carefully clean the sample line and press [OK].
- At prompt "Attach new Vacutainer", attach a 50 mL Falcon tube and press [OK]. This tube can be reused. A twisting action will help to push the Falcon tube over the O-ring and into position.
- Secure the Falcon tube by pushing it into the vertical position.
- At prompt "Finished CTC01" "Back to Main Menu", press [OK] then [Continue] to return to the main menu on the screen.

The instrument is now ready to process another sample.



Important:

CTCs have a short half-life (minutes rather than hours, although estimations vary), therefore it is recommended that the harvest is used immediately for the desired downstream application to preserve the CTC number and viability.



Warning:

The sample processing protocol CTC01 does not allow for in-cassette staining. Please use the individual protocols as described further in Section 8 to allow for this process.

8.3 Operation of Individual Protocols

Samples should be run using individual protocols when in-cassette staining of captured cells is required.

8.3.1 Priming / PX2_PF

The priming process prepares a new Parsortix GEN3P 6.5 Cell Separation Cassette by filling it with buffer solution.

Note: If the Parsortix instrument was not cleaned after the last operation or within the last 24 hours, perform the cleaning protocol as described in Section 8.3.5 **before** beginning the priming protocol.

To run the priming protocol:

- In the instrument's main menu screen, select the protocol PX2_PF using the scroll arrows, and press [Run] then [Start].
- The instrument will run for ~4 minutes.
- At prompt "Insert New Cassette" "Ready?":
 - Remove the old cassette from the clamp and properly dispose of it.
 - Insert a new cell separation cassette and close the clamp. Press [OK].
- The instrument will run for ~7 minutes.

- At prompt "Finished PF" "Back to Main Menu", press [OK] and [continue] to return to the main screen.

8.3.2 Blood Separation / PX2_S99F

The separation process is initiated by applying 99 mbar pressure into the sample tube. Once the sample has been processed, the sample line and cell separation cassette are rinsed with PBS.

After completing the priming protocol (section 8.3.1):

- Verify that the harvest valve is in the "SEP" position (Figure 17).
- In the instrument's main menu screen, select the protocol PX2_S99F using the scroll arrows, and press [Run] then [Start].
- At prompt "Rinse Vacutainer" "Start?", verify that a 50 mL Falcon tube is attached to the sample mount and press [OK].
- At prompt "Preparing Sample" "Attach Vacutainer...", remove the 50 mL Falcon tube from the sample mount. Wipe the sample line and top of the sample mount using an alcohol-soaked wipe.
- Attach the sample tube to the sample mount, secure into the vertical position (Figure 19) and press [OK].
- At prompt "Preparing Sample" "Start?", press [OK].
- The system will automatically stop once the whole sample has been processed. There should be only trace amounts of blood left in the sample tube and the cassette should appear visually clear of blood.
- At prompt "Finished S99F" "Back to Main Menu", press [OK] and [continue] to return to the main screen.

8.3.3 Pre-harvest Flush / PX2_preH

This protocol flushes the internal tubing with the cleaning reagent and then rinses with PBS .

After completing the separation protocol (section 8.3.2):

- In the instrument's main menu screen, select the protocol PX2_preH using the scroll arrows, and press [Run] then [Start].
- At prompt "Insert Cleaning Cass.", open the cassette clamp and remove the cell separation cassette. Replace with a Parsortix GEN3C Cleaning Cassette and press [OK].
- At prompt "Waste empty?", confirm that the waste reservoir bottle is less than 400 mL full and press [OK].
- At prompt "Finished preH" "Back to Main Menu", the flush is complete. Press [OK] and [continue] to return to the main menu.

8.3.4 Cell Harvest / PX2_H

The cell harvest protocol retrieves the captured cells from the cell separation cassette in a 210 µL aliquot that can be collected into . PBS is passed through the cassette in the reverse direction. There is also an option to further rinse the cassette with 1 mL PBS.

After completing the pre-harvest flush protocol (section 8.3.3):

- Remove the cleaning cassette from the cassette clamp and reinsert the cell separation cassette.
- In the instrument's main menu screen, select the protocol PX2_H using the scroll arrows, and press [Run] then [Start].
- At prompt "Rotate Valve..." "Anticlockwise", turn the harvest valve to the "HAR" position (Figure 18) and press [OK].
- At prompt "Harvest" "Start?", remove the harvest line from the harvest waste tube and clean it with an alcohol-soaked wipe.
- Place the tip of the harvest line into a collection vessel (e.g. an Eppendorf tube) and press [OK].
- Place the harvest line back into the respective waste tube and store the collection vessel containing the harvest sample as appropriate.

NOTE: If using fluorescent cells, store away from light.

- At prompt "Rotate Valve..." "Clockwise", turn the harvest valve to the "SEP" position (Figure 16) and press [OK].
- At prompt "Finished H" "Back to Main Menu", press [OK] and [continue] to return to the main menu.

8.3.5 Cleaning / PX2_C / PX2_CT

The Parsortix instrument must be cleaned within 24 hours prior to processing a sample. If the instrument has not been used for more than 24 hours, or an instrument re-start was performed, run the cleaning protocol to reset the system, ready for the next process.

Two cleaning protocols are available:

- A full cleaning process (**PX2_C**) is necessary after in-cassette staining, or after other protocols that use reagent lines 1-6. It is also recommended to perform a full clean before priming for experiments involving in-cassette staining. The full process takes approximately 1 hour.
- When reagent lines 1-6 are not used, a short cleaning process (**PX2_CT**) must be performed at the end of the cell harvest. Furthermore, a short cleaning process can be used when cells are not being harvested and the cassette is not being stained. This process takes approximately 45 minutes to complete.

To run the cleaning protocol:

- In the instrument's main menu screen, select the protocol PX2_C or PX2_CT using the scroll arrows, and press [Run] then [Start].
- At prompt "Insert Cleaning Cass", confirm that a cleaning cassette is inserted in the clamp and press [OK].

- At prompt "Waste empty?", confirm that the waste reservoir bottle is less than 400 mL full and press [OK].
- At prompt "Finished CT" "Back to Main Menu", or "Finished C" "Back to Main Menu" press [OK] and [continue] to return to the main menu on the screen.
- Remove the 50 mL Falcon tube from sample mount, use an alcohol-soaked wipe to carefully clean the sample line, and attach a clean 50 mL Falcon tube to the sample mount.
- Empty the fluids from the harvest waste tube.
- In the case of a full clean process (PX2_C), discard the reagent tubes 1-6 and clean the outside of the lines with an alcohol-soaked wipe to remove residual cleaning fluid. Replace the reagent tubes with new ones.

8.3.6 Buffer Replacement / PX2_LOAD

Each time the buffer reservoir bottle is refilled or replaced the protocol PX2_LOAD must be run to expel any air bubbles that have been introduced into the tubing.

- In the instrument's main menu screen, select the protocol PX2_LOAD using the scroll arrows, and press [Run] then [Start].
- At prompt "Waste empty?", confirm that the waste reservoir bottle contains less than 400 mL and press [OK].
- At prompt "Finished LOAD" "Back to Main Menu", the protocol is complete. Press [OK] and [continue] to return to the main menu on the screen.

8.3.7 In-cassette Immunofluorescent Staining

Blood separation can be followed by immunofluorescence (IF) staining of the captured cells, within the cell separation cassette, for visualization and enumeration under a microscope.

The captured cells can be stained in the cassette using the instrument's reagent tubes (1-6) and the in-cassette staining protocols PX2_Stain1, PX2_Stain2, PX2_Stain3 and PX2_Stain4.

Please contact your local ANGLE technical support provider with any questions about protocols and applications and to obtain an in-cassette staining application note with detailed description of these protocols. Antibodies, their concentrations, and incubation times should be tested and optimised by the end user before use.

9. Routine Maintenance Procedures



Warning:

Contact your local ANGLE technical support provider in the event that damage to any component of the Parsortix system is found or suspected.

9.1 Weekly Maintenance

To maintain instrument cleanliness and ensure optimal performance of the Parsortix system, the weekly maintenance procedure must be adhered to. It is recommended that the weekly maintenance procedure always be performed on the same day of the week. The procedure will take approximately 1.5 hours to complete. All bottles and tubes removed from the instrument should be emptied and washed or autoclaved prior to refilling and reuse on the instrument.

9.1.1 Check and Clean Instrument Components

- Check that the tubing connecting the instrument to the clamp is not kinked.
- Check that the two waste lines (connecting the waste reservoir bottle to the instrument) and the buffer line (connecting the buffer reservoir bottle to the instrument) are not kinked.
- Check that the filters on the buffer and waste reservoirs are in place and are not contaminated or damaged (filters should be colourless). Replace if necessary.
- Check that there are no visible leaks around the instrument, particularly at the cassette clamp. If leaks are observed, contact your local ANGLE technical support provider.
- Use a deionised water-soaked wipe to gently clean the clamp gaskets and its surrounding.
- Check that the O-rings on the sample mount are in place, clean and in good condition. If the O-rings appear to be damaged, replace them with the spare O-rings provided.
- Clean the external cover of the instrument with a weak detergent, 70% Ethanol or isopropanol followed immediately by a water damp towel.
- If necessary, remove and clean the drip tray from around the sample mount area.

9.1.2 Replace Reagents

- Ensure that a clean 50 mL Falcon tube is attached to the sample mount.
- Remove and replace all waste and reagent bottles and tubes as described in Section 7.5.

9.1.3 Run Maintenance Protocol

- In the instrument's main menu screen, select the protocol PX2_Maintenance using the scroll arrows, and press [Run] then [Start].
- At prompt "Waste empty?", confirm that the waste reservoir bottle is less than 400 mL full and press [OK].
- At prompt "Clean rgt as buffer?", replace the buffer reservoir bottle with a new bottle filled with minimum 50 mL of cleaning reagent and press [OK].

- After 10 minutes, at prompt "1xPBS as buffer", remove the bottle containing the cleaning reagent and wipe the outside of the tubing line to avoid carry-over of any detergent. Replace with the buffer reservoir bottle removed at the previous step, which should be filled with 250 mL of 1xPBS and press [OK].
- At prompt "Insert New Cassette" "Ready?", open the cassette clamp and remove the existing cassette. Insert a new Parsortix GEN3C cleaning cassette into the clamp and press [OK].
- The remainder of the protocol will run automatically and will take 1 hour and 15 minutes.
- At prompt "Finished Maintenance" "Back to Main Menu", press [OK] and [continue] to return to the main menu on the screen.

9.2 Monthly Maintenance

In addition to the weekly maintenance, perform the following monthly:

- Replace all 15 mL reagent tubes on the instrument with new ones.
- Replace the 50 mL Falcon tube (harvest waste container) with a new one.
- Replace the priming reagent (ethanol).

9.3 Annual Maintenance

Your local ANGLE technical support provider will contact you to arrange a visit as part of the pre-agreed service package.

10. Troubleshooting

The following table describes the recommended actions to address issues during operation of the Parsortix system. Contact your local ANGLE technical support provider if further advice is required, problems persist, or kinks, leaks or other damage is observed.

Issue	Action
Instrument does not switch on	1. Check there is an electrical supply to the lab. 2. Check that the instrument is connected to a power outlet. 3. With the instrument switched off on the side panel, disconnect it from the power outlet, wait 15 seconds then reconnect and turn on the instrument. 4. If the instrument does not turn on, switch it off again at the side panel. 5. Inspect the fuse holder and the supply fuse located on the left-hand side panel of the instrument. Replace if necessary. If the issue is not resolved, contact your local ANGLE technical support provider.

Issue	Action
Instrument is unresponsive to key presses, or the main screen is blank	1. Switch the instrument off, wait for 15 seconds and then switch it on again and observe the message "Parsortix system starting" on the main screen. 2. Once the instrument is responsive, run a PX2_CT before resuming normal operations. If the issue persists, contact your local ANGLE technical support provider.
Unable to select protocols on the main screen	1. Switch the instrument off, wait for 15 seconds and then switch it on again and observe the message "Parsortix system starting" on the main screen. If the issue persists, contact your local ANGLE technical support provider.
Error messages on the main screen e.g., "Error loading protocols", "Communication error," or "Service due"	1. Follow on-screen prompts where possible. If the issue persists, contact your local ANGLE technical support provider.
Discolorations in the buffer, priming, or cleaning reagent reservoir bottles	1. Verify that only the specified reagents have been used (see Section 7.5). 2. Replace discoloured reservoir bottles (and lines if possible) with clean ones. If the issue persists, contact your local ANGLE technical support provider.
The system stalls, the message "Waiting for pump" is displayed, and there is no fluid dripping into the waste reservoir for longer than a minute	1. Check that the sample tube or Falcon tube is properly attached to the sample mount and that the O-ring is not pinched or damaged. 2. Check that the harvest valve is fully turned to the "SEP" position. 3. Press [Abort] to return to the main screen and follow the Standard Recovery Procedure (Section 10.1). 4. Check that the buffer, priming reagent, and cleaning reagent lines are properly connected. 5. Ensure that the waste reservoir bottle volume is <400 mL. 6. Check that the lid filters on the buffer, priming reagent, cleaning reagent, and waste bottles are dry. Replace if necessary. If the issue is not resolved, contact your local ANGLE technical support provider.

Issue	Action
Instrument is not taking up sample	1. If there is a continuous loud buzzing: i. Check that the sample tube is properly attached. ii. If the noise continues, turn off the instrument, remove the sample tube and inspect the mount O-ring. Replace if necessary. 2. Check that the harvest valve is fully turned to the “SEP” position. 3. Ensure the waste bottle volume is < 400 mL. 4. Tap the sample tube to agitate the sample and observe if fluid is being taken up. If the issue is not resolved there may be a blockage in the flow path; contact your local ANGLE technical support provider.
Fluid is leaking out of the instrument during sample processing, maintenance, or cleaning	Contain and handle the spillage following local Health and Safety protocols and wearing proper PPE. Press [Abort] to return to the main screen and follow the Standard Recovery Procedure (Section 10.1). Clean the instrument and the surrounding area. 1. Check and tighten all connections near the leak position. 2. Check all lines near the leak position for visual damage. If damage is found, contact your local ANGLE technical support provider. 3. Check the cassette for visible damage. 4. Ensure the cassette is inserted correctly in the clamp. 5. Check waste and other fluids levels; empty or fill as necessary. 6. Check the harvest waste tube level and empty if necessary. 7. Remove the sample tube and check the O-ring for visible damage. Replace if necessary. 8. Check the fluid volume in the sample tube; if it is >10 mL, contact your local ANGLE technical support provider. 9. Perform the protocol PX2_CT (Section 8.3.5). If the issue persists, contact your local ANGLE technical support provider.

Issue	Action
Ethanol, 1X PBS, or cleaning reagent is not being taken up	1. Check that the harvest valve is fully turned to the "SEP" position. 2. Ensure that the affected bottle contain enough reagent (Section 7.5). 3. Check that the connection(s) to the affected bottle are tight. 4. Inspect the line of the affected bottle for kinks. If there is a kinked line, contact your local ANGLE technical support provider. 5. Replace the affected bottle lid filters. If the issue persists, contact your local ANGLE technical support provider.
Liquid is left in the bottom of the sample tube after completion of sample processing	Contact your local ANGLE technical support provider.
Observation or suspicion of damage to any component of the instrument during routine operation or inspection	Contact your local ANGLE technical support provider.

10.1 Standard Recovery Procedure

The standard recovery procedure safely shuts down and restarts the Parsortix instrument.

- If needed, return to the main menu by pressing and holding [Abort] then [Continue].
- Switch off the instrument by pressing [System] then [Shutdown]. At prompt "Shutdown: confirm?", press [Yes]. When the message "Please power off" is displayed, wait for 15 seconds, and then switch the instrument off using the main ON/OFF switch located at the left-hand side panel.
- After another 15 seconds, switch the instrument on using the main ON/OFF switch.
- Run a cleaning cycle by selecting "PX2_CT" and press [Run] then [Start]. Follow the instructions for the cleaning process in Section 8.3.5.

11. Technical Support

For customer support, contact your local ANGLE technical support provider or distributor. ANGLE's head office details are in Section 16.

12. Spare Parts

The following spare parts may be obtained and fitted by the user:

Item	ANGLE catalogue number
Parsortix PR1 with in-cassette staining operating manual	PR1WICS-OM-A Parsortix PR1 With in-cassette Staining Operating Manual
Ten disposable Parsortix GEN3C Cleaning Cassettes	CAS-3C-RUO-CC
Ten disposable Parsortix GEN3P 6.5 Cell Separation Cassettes	CAS-3P-RUO-65
Two replacement O-rings for blood sample connection	SPP-00230
One three-port bottle lid with filter and port plug fitted (for buffer reservoir) One three port bottle lid with filter fitted (for waste reservoir)	SPP-00239
Six 15 mL reagent tube caps with ferrules fitted	SPP-00044
Three 50 mL reagent tube caps with ferrules fitted	SPP-00045
One Parsortix PR1 system power supply	SPP-00052
One UK, US, or European power lead for power supply	SPP-00050 (UK lead), SPP-00051 (US lead), SPP-00055 (European Lead)
Two rubber non-slip mats	SPP-00047 (r/hand mat), SPP-00048 (l/hand mat)

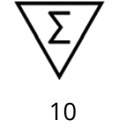
In addition, the filters on the waste reservoir lid and the reagent reservoir lid may need regular changing when observed to be damaged or contaminated (refer to section 9.1 Weekly Maintenance). For the waste reservoir lid Cole-Parmer PTFE Syringe Filters, Non-Sterile; 0.20 µm, 15 mm Diameter must be used (catalogue number: WZ-29550-08). For the buffer reservoir lid Cole-Parmer Nylon Chromatography Syringe Filter, 0.20 µm, 13mm Diameter must be used (catalogue number: 15945-10).

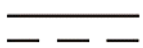
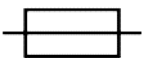
12.1 Material Compatibility

Before using any chemicals and reagents not listed in this document contact your local ANGLE technical support provider or distributor to ensure compatibility with the Parsortix instrument.

13. Definition of Symbols

The following symbols may appear on the product labelling:

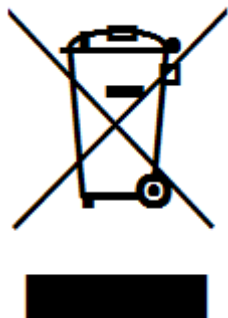
	READ INSTRUCTIONS	Read the instruction manual for description of principles of operation and details of potential hazards.
	BIOHAZARD	This instrument may become contaminated with biohazardous material.
	CE MARK	Indicates compliance with a range of European Directives as set out in the accompanying Certificate of Conformity.
	MANUFACTURER	Name and address of the instrument manufacturer.
	CAUTION	Consult the instructions for use for important warning or cautionary information.
	WEEE	Do not dispose of in domestic waste.
	LOT NUMBER	Manufacturer's lot number for traceability of components.
	SERIAL NUMBER	Manufacturer's serial number for instrument identification.
	SINGLE USE ONLY	The components must not be used more than once to avoid the risk of cross-contamination.
	DO NOT USE IF PACKAGING IS DAMAGED	Do not use the labelled component if the packaging is already open in order to avoid the risk of contamination.
	KEEP AWAY FROM SUNLIGHT	Parts labelled are sensitive to sunlight and should be stored away from sunlight.
	FRAGILE	Indicates that the contents of a package or container are fragile and should be handled with care.
	CONTAIN SUFFICIENT FOR 10 TESTS	Indicates the number (10 as displayed) of tests (or related consumable items) supplied.

	DIRECT CURRENT	Indicates direct current supply to the equipment.
	FUSE	Location, value and characteristics of the external system fuse.
	THIS WAY UP	Preferred packaging orientation for storage and shipping.
	KEEP DRY	Packaging should be kept dry at all times during storage and shipping.
	HARVEST/SEPARATE	A switchable valve to select cell separation or cell harvesting mode.
	NATIONALLY RECOGNIZED TESTING LABORATORY (NRTL) SYMBOL	The NRTL certificate for the device provides evidence of compliance with required standards for the U.S. market. The device has been assessed by TÜV SÜD for compliance with the USA and Canada safety standards, as shown on the NRTL certificate.

14. Disposal of Electronic Equipment

It is important to understand and follow all laws regarding the safe and proper disposal of electrical instrumentation.

Disposing of this product correctly will save valuable resources and prevent any potential negative effects on human health and the environment which could otherwise arise from inappropriate waste handling. If you are unsure of your national requirements with respect to disposal, please contact your local authority or your local ANGLE technical support provider for further information.



The symbol of a crossed-out wheeled bin on the product means that the device must not be disposed via the general waste collection system.

In the European Union, this symbol is required in accordance with the Waste Electrical and Electronic Equipment (WEEE) Directive 2012/19/EC of the European Union on all devices placed on the European market after 13 August 2005.

Please contact your local ANGLE technical support provider for appropriate decontamination information and details on the take back program which will facilitate the proper collection, treatment, recovery, recycling, and safe disposal of the device.

15. Certificate of Decontamination

An electronic copy of this certificate is available from ANGLE; contact your local ANGLE technical support provider or distributor.

ANGLE will not accept returned equipment without a valid Return of Merchandise Authorisation (RMA) number and a fully completed certificate of decontamination.

16. Legal Information

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Document Revision History

Version	Date	Revision	Author
A1	13-06-2024	First draft for review. Based on PR1-OM-E Parsortix PR1 User Manual, with format and layout changes harmonised with approved new PR1 OM.	SP, KB, BT
A2	13-06-2024 09-07-2024 07-10-2024	Protocols updated to include in-cassette staining information. Section 3 & 7.7 – updated text for sample tubes that can be used for blood collection vs. blood processing. Review of formatting to harmonise with PR1 OM.	SP, KB, BT
A3	18 Nov 2024	Updates to section 3 and section 7.5 to reflect availability of consumables and reagents in the US/ ROW. Updateds to Spare Parts table in section 12 Final document for DocuSign	SP
A4	20 May 2025	Updated format and changes to number of O-rings in accessories	SP
A	19 June 2025	Approved version	SP

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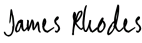
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