Parsortix® PC1 Instrument CE Instructions for Use

Intended Use: The Parsortix® PC1 system is an in vitro diagnostic device intended to enrich circulating tumor cells (CTCs) from peripheral blood collected in K₂EDTA tubes from patients diagnosed with metastatic breast cancer. The system employs a microfluidic chamber (a Parsortix cell separation cassette) to capture cells of a certain size and deformability from the population of cells present in blood. The cells retained in the cassette are harvested by the Parsortix PC1 system for use in subsequent downstream assays. The end user is responsible for the validation of any downstream assay. The standalone device, as indicated, does not identify, enumerate or characterize CTCs and cannot be used to make any diagnostic/prognostic claims for CTCs, including monitoring indications or as an aid in any disease management and/or treatment decisions.

For In Vitro Diagnostic Use
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1. **Intended Use**

   **For In Vitro Diagnostic Use**

   The Parsortix® PC1 system is an in vitro diagnostic device intended to enrich circulating tumor cells (CTCs) from peripheral blood collected in K$_2$EDTA tubes from patients diagnosed with metastatic breast cancer. The system employs a microfluidic chamber (a Parsortix cell separation cassette) to capture cells of a certain size and deformability from the population of cells present in blood. The cells retained in the cassette are harvested by the Parsortix PC1 system for use in subsequent downstream assays. The end user is responsible for the validation of any downstream assay. The standalone device, as indicated, does not identify, enumerate or characterize CTCs and cannot be used to make any diagnostic/prognostic claims for CTCs, including monitoring indications or as an aid in any disease management and/or treatment decisions.

2. **References**

   The following documents are referenced:
   - *MBC CE-OM-C Parsortix PC1 CE MBC-01 Metastatic Breast Cancer Kit Instructions for Use*
   - *ICT CE-OM-C Parsortix PC1 CE ICT-01 Instrument Control Test Kit Instructions for Use*

3. **Summary and Explanation**

   The Parsortix PC1 instrument used in combination with the Parsortix PC1 MBC-01 Metastatic Breast Cancer Kit (MBC-01 kit) enables the enrichment and isolation of CTCs from a peripheral blood sample drawn from metastatic breast cancer patients into K$_2$EDTA tubes and provides them as free cells suspended in buffer to allow a variety of subsequent downstream evaluations in accordance with Section 1 above. The Parsortix PC1 ICT-01 Instrument Control Test Kit (ICT-01 kit) is used periodically (weekly) in conjunction with the Parsortix PC1 instrument and the MBC-01 kit to verify acceptable Parsortix PC1 instrument performance. All three of these components (the Parsortix PC1 instrument, MBC-01 kit, and ICT-01 kit) comprise the Parsortix PC1 system (device). Refer to the Instructions for Use (IFU) for the MBC-01 and ICT-01 kits for additional information. These IFUs can be found here: [www.angleplc.com/ivd-ifu](http://www.angleplc.com/ivd-ifu)

4. **Principle of Operation**

   The Parsortix PC1 instrument is intended for use by suitably trained users in a clinical laboratory setting and must be used in conjunction with the MBC-01 and ICT-01 kits. The instrument contains an on-board buffer reservoir, a cleaning fluid reservoir, a priming fluid reservoir and a waste reservoir to capture spent fluids and non-retained blood components.

   Blood from a sample collection tube or fluid from an ICT sample is routed through a GEN3P6.5IVD cell separation cassette (separation cassette) under controlled pressure conditions to enable CTC capture. The typical blood separation rate is approximately 5mL per hour. A separate harvest line, attached to a harvest waste tube, is used for the harvesting of the cells captured in the separation cassette so that they may be evaluated using subsequent downstream assays.

   Buffer, priming fluids and cleaning fluids are drawn from the external bottles and tubes and routed through the internal fluidic components including the separation cassette. This enables:
• Priming of the system before use to remove air from the internal components and the separation cassette;
• Rinsing (with buffer) of the tubing to ensure that the entire blood sample has gone through the separation cassette to complete a separation with minimal sample wastage; and
• Thorough cleaning of the system after use in preparation for the next operational cycle.

The Parsortix PC1 instrument enables captured CTCs to be harvested from the separation cassette into an external vessel (e.g. a microfuge tube) for further, user defined, subsequent downstream evaluation.

5. Materials Provided

The key components of the Parsortix PC1 instrument (Figure 1) are listed below.

*Figure 1. Overview of key components of the Parsortix PC1 instrument.*

1. Screen and control panel
2. Separation cassette clamp
3. 500mL waste reservoir
4. 250mL buffer reservoir
5. Sample mount
6. 100mL priming reagent reservoir
7. 250mL cleaning reagent reservoir
8. Harvest valve with Harvest line/waste tube

The shipping carton contains the following items:
• One (1) Parsortix PC1 instrument pre-loaded with the application software and the following core protocol files: **MBC01, PX2_CLEAN, PX2_LOAD** and **PX2_PRIMING**;
• Two (2) non-slip pads;
• One (1) drip tray;
• One (1) flushnut tool;
• One (1) manual flush kit;
• One (1) 500mL glass bottle, two (2) 250mL glass bottles, one (1) 100mL glass bottle and lid assemblies;
• Three (3) 50mL Falcon tubes (for harvest waste collection) and lid assemblies;
• One (1) 50mL tube rack;
• One (1) separation cassette clamp;
• Two (2) sets of replacement O-rings for sample mount;
• Two (2) sets of replacement filters for the reagent and waste reservoir lid assemblies;
• One (1) external main voltage power supply (110V/240V automatically adjustable) and leads for use in Europe and the UK;
• Printed [and CD format] Instructions for Use.

6. Materials Required, Not Provided

Equipment:
• Pipette-aid

Reagent and consumables:

<table>
<thead>
<tr>
<th>Part Number</th>
<th>Manufacturer</th>
<th>Product</th>
</tr>
</thead>
<tbody>
<tr>
<td>ICT-01</td>
<td>ANGLE</td>
<td>Parsortix PC1 ICT-01 Instrument Control Test Kit</td>
</tr>
<tr>
<td>MBC-01</td>
<td>ANGLE</td>
<td>Parsortix PC1 MBC-01 Metastatic Breast Cancer Kit</td>
</tr>
<tr>
<td>352098</td>
<td>BD/Falcon</td>
<td>50mL Falcon Tubes</td>
</tr>
<tr>
<td>143205WR</td>
<td>Steris Life Sciences</td>
<td>ProKlenz® 120</td>
</tr>
<tr>
<td>Varies</td>
<td>Varies</td>
<td>Sterile 100mL serological pipette</td>
</tr>
<tr>
<td>Varies</td>
<td>Varies</td>
<td>Sterile, filtered PBS (500mL Bottles) without Ca2+/Mg2+ (PBS buffer)</td>
</tr>
<tr>
<td>Varies</td>
<td>Varies</td>
<td>Deionized Water (1 Litre Bottles)</td>
</tr>
<tr>
<td>Varies</td>
<td>Varies</td>
<td>Absolute Ethanol (99.5%)</td>
</tr>
<tr>
<td>Varies</td>
<td>Varies</td>
<td>Sodium Hypochlorite Bleach</td>
</tr>
</tbody>
</table>
7. Warnings and Precautions

- **WARNING:** Instructions for use and labelling for the Parsortix PC1 instrument, MBC-01 kit and ICT-01 kit must be followed at all times.

- **WARNING:** Following the Parsortix PC1 instrument, ICT-01 and MBC-01 kit Instructions for Use will ensure optimum device performance. It is the responsibility of the user to ensure instrument performance is adequate for specific downstream evaluation.

- **WARNING:** Do not use GEN3C cleaning cassettes in place of GEN3P6.5IVD cell separation cassettes for the processing of ICT samples or blood samples on the Parsortix PC1 instrument.

- **WARNING:** Blood sample processing should not be conducted as per the MBC-01 kit Instructions for Use using a Parsortix PC1 instrument that has not undergone the weekly maintenance, including a successful ICT procedure as described in the ICT-01 kit Instructions for Use.

- **WARNING:** The Parsortix PC1 instrument together with the ICT-01 and MBC-01 kits is designed for use in a high complexity testing laboratory environment, as defined by CLIA. It must be situated and operated only in facilities with the specialized infrastructure and general equipment required for clinical laboratory operations, including those with blood disposal facilities following universal precautions. Users must follow these universal precautions and use specified laboratory safety equipment. All chemicals and all consumables that had contact with blood must be disposed of using adequate precautions and in accordance with local, state, and national regulations.

- **WARNING:** The electromagnetic environment that this device is to be located within must be evaluated prior to the operation of the device. The Parsortix PC1 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.

- **WARNING:** The Parsortix PC1 instrument will be installed, set-up and commissioned by trained personnel from ANGLE. Do not connect external equipment to the instrument, except under the specific instruction of ANGLE technical staff. The connection points on the instrument are for service use by trained personnel only.

- **WARNING:** The transparent lines/pipes/tubing are the most vulnerable part of the instrument and they can bend or kink easily, resulting in instrument malfunction.

- **WARNING:** Risk of aerosol. Never attempt to remove a sample tube from the sample mount or any cassette from the clamp assembly while instrument is in operation.
• **WARNING:** The Parsortix PC1 GEN3C cleaning cassettes and GEN3P6.5IVD cell separation cassettes (collectively cassettes) are fragile and must be handled with care. Always handle cassettes by the edges and avoid applying pressure to its surfaces.

• **WARNING:** Follow Health and Safety and Precautionary statements as described in the Parsortix PC1 Instrument Instructions for Use.

Operating the Parsortix PC1 instrument involves two main potential hazards for the user (*Table 2*):

*Table 2. Two main risks to the user associated to the operation of the Parsortix PC1 instrument*

<table>
<thead>
<tr>
<th>Risk</th>
<th>Description</th>
<th>Action to minimize risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biohazards</td>
<td>Handling blood that may carry bloodborne pathogens</td>
<td>Exposure during sample handling: establish appropriate operating procedures, use containment and personal protective equipment and consider vaccinations.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Exposure during equipment operation: Carefully mount and remove sample tubes and wear personal protective equipment. Clean spillages as described in this section.</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Handling of waste: ensure that the waste reservoir is prepared as instructed in <em>Section 10.5.1</em> and that the waste material produced is handled and disposed of appropriately. Wear personal protective equipment.</td>
</tr>
<tr>
<td>Chemical hazard</td>
<td>Exposure to chemicals that may be caustic, noxious, toxic, volatile or flammable</td>
<td>Establish operational procedures and risk-assessment: storage, handling, deployment, and disposal of chemical reagents in accordance with hazardous for health instructions of each reagent. Wear personal protective equipment (PPE).</td>
</tr>
</tbody>
</table>

8. **Limitations**

- For *In Vitro* Diagnostic Use.

- The standalone device, as indicated, is not intended for cell enumeration.

- The Parsortix PC1 Instrument must only be used in conjunction with a Parsortix PC1 ICT-01 Instrument Control Test Kit (ICT-01 kit) and a Parsortix PC1 MBC-01 Metastatic Breast Cancer Kit (MBC-01 kit) and in accordance with the Intended Use set out in the instructions accompanying the equipment and kits.

- The variability of the number of CTCs and other cells harvested by the device, including insufficient number of CTCs or even no CTCs collected, may impact the success of any subsequent analysis.

Date: 09 January 2023
The performance characteristics of this device have not been established for general downstream diagnostic assays and end users must validate use with any subsequent tests and collection devices.

The standalone device, as indicated, is not intended for diagnostic, prognostic, or monitoring use with circulating tumour cells, including as an aid in any disease management and/or treatment decisions.

The use of the device is indicated for previously diagnosed metastatic breast cancer patients.

Results from the standalone device, as indicated, do not provide information to the patient regarding their current state of health.

The standalone device, as indicated, does not diagnose any health conditions and is not a substitute for visits to a doctor or other healthcare professional.

The standalone device provides material (circulating tumour cells) that must be processed/analysed using additional independent methods (referred to as subsequent downstream assays). Subsequent downstream assays must be validated by the end user, as needed.

CTC identification or enumeration is not provided by the standalone device as indicated. The Parsortix PC1 device, as indicated, is intended for use on patients already diagnosed with metastatic breast cancer. No clinical decisions (diagnostic, prognostic, predictive or any treatment) should be made solely on the basis of the output obtained with the Parsortix PC1 device. It is the responsibility of the user to ensure validation of the downstream analysis is completed in conjunction with other IVD assays/tests and/or in accordance with clinical laboratory requirements before clinical assessment.

An acceptable ICT result does not guarantee that circulating tumour cells (CTCs) will be captured from a blood sample.

Refer to the ICT CE-OM-C Parsortix PC1 CE ICT-01 Instrument Control Test Kit Instructions for Use and MBC CE-OM-C Parsortix PC1 CE MBC-01 Metastatic Breast Cancer Kit Instructions for Use documents for further limitations related to the device. These IFUs can be found here: www.angleplc.com/ivd-ifu

9. Storage and Handling
The Parsortix PC1 instrument must be stored and operated according to the following environmental conditions:

- Operation: 18°C to 25°C at 95 – 105 kPA. Maximum operating altitude 2000m.
- Storage: 0°C to 40°C at 95 – 105 kPA.

The Parsortix PC1 instrument complies with the emission and immunity requirements described in the IEC 61326 standard. 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 PC1 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 PC1 instrument should not be placed on the same bench as a centrifuge to minimize vibration.

The total shipping carton dry weight, including Parsortix PC1 instrument and accessories described, is 19kg.
The shipping box dimensions are 58cm length, 50cm width and 50cm height.
The Parsortix PC1 system set up on the bench has the following dimensions: 46cm length, 36cm width and 28cm height. The bench space required is 80cm length, 50cm width and 50cm height.
The Parsortix PC1 instrument power requirement is 1x outlet, 110V (minimum voltage).

10. Instrument Operating Procedures
The Parsortix PC1 instrument will be installed, set-up and commissioned by trained personnel from ANGLE. Only after a successful set-up and qualification by qualified ANGLE personnel is the system ready for sample processing.

10.1 Instrument Start-Up
The instrument can be turned on and off using the power switch on the left side of the instrument (Figure 2). The internal instrumentation will be heard moving as the start-up sequence takes place. The display screen will report the progress before presenting the main menu (Figure 3). Reagent and waste levels in the respective reservoirs need to be checked before proceeding with further instrument operations (see Section 10.5).

*Figure 2. Parsortix PC1 Instrument Rear Panel Showing Power Switch and Fuse*
10.2 User Interface Screen and Keypad

The user interface screen (Figure 3) 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, invoke various functions as displayed on the screen above each button.

Figure 3. Parsortix PC1 system User Interface Screen and Keypad

The main menu allows access to the protocols installed on the instrument. To browse the list of available protocols, the user needs to press the keys for left [<<] and right [>>] scroll to select a protocol, and then press [Run] to activate the selected protocol. When the system is running, one soft key will be allocated the function [Abort]. Pressing and holding [Abort] will stop the running of the selected protocol and return the user to the main menu. Following an [Abort] action, the Standard Recovery Procedure described in Section 11.1 must be performed.

10.3 Cleaning Solution Preparation

The cleaning solution used on the Parsortix PC1 instrument consists of 10% v/v ProKlenz 120. Use caution and wear appropriate PPE when handling ProKlenz 120.

- Dispense 900mL deionized water into a 1-liter (1000mL) Duran type bottle or another appropriate container. Alternatively, remove 100mL of deionized water from a new 1-liter (1000mL) deionized water container.
- Using a sterile 100mL serological pipette and a pipette aid, aspirate 100mL of ProKlenz 120 from the 5-gallon container.
- Dispense the 100mL of ProKlenz 120 into the 900mL of deionized H2O.
- Secure lid on the bottle/container and invert three times to mix.
- Label the bottle with the contents (e.g., 10% ProKlenz) and an expiry date (2 weeks from the current date).

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

10.4 Parsortix PC1 GEN3 Cassettes

Two types of Parsortix PC1 cassettes are required for the operation of the Parsortix PC1 instrument (Figure 4):

- a GEN3C cleaning cassette; used for the cleaning processes. **NOTE:** This cassette may be used for up to ten (10) individual cleaning cycles or for up to a period of one week after first use.
- a single use GEN3P6.5IVD cell separation cassette; used for the processing of blood samples or ICT samples.
Both cassette types are supplied as consumables by ANGLE in a Parsortix PC1 MBC-01 Metastatic Breast Cancer Kit and/or in a Parsortix PC1 ICT-01 Instrument Control Test Kit. Refer to the *ICT CE-OM-C Parsortix PC1 CE ICT-01 Instrument Control Test Kit Instructions for Use* and *MBC CE-OM-C Parsortix PC1 CE MBC-01 Metastatic Breast Cancer Kit Instructions for Use* documents for further information. These IFUs can be found here: [www.angleplc.com/ivd-ifu](http://www.angleplc.com/ivd-ifu)

*Figure 4.* Parsortix PC1 cell separation cassettes with packaging.

### 10.4.1 Cassette Removal and Loading

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

When handling the cassette clamp, position your body in front of the instrument and lean towards the instrument. This will limit the distance a user can pull the clamp assembly towards themselves and help prevent kinked lines.

- Ensure the clamp assembly is positioned on the top of the instrument as shown below:
- Open the latch on the left-hand side of the clamp.
- While holding the clamp assembly tightly, lift the clamp assembly up off of the instrument and carefully flip it over so that the tubing attached to the top of the clamp is now facing towards the instrument. Take care when handling the clamp not to pull or twist the inlet or outlet lines.
- Carefully open the clamp assembly.

- Remove the cassette inside the clamp and retain or dispose of as required.
- Choose the appropriate new GEN3 cassette type (GEN3C or GEN3P6.5IVD), remove it from the package.
- Hold cassette vertically so that the open notch is in the upper left-hand corner.
• Position the new cassette in the clamp so that the peg in the upper left-hand corner of the clamp assembly lines up with the notch in the upper left-hand corner of the cassette. Ensure that the lower left-hand corner of the cassette also engages on the corresponding peg in the clamp.

• Close the left-hand side of the clamp over the cassette, making sure the cassette remains in place.

• Secure the latch.

• Flip the clamp assembly 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. Take care when handling the clamp not to pull or twist the inlet or outlet lines. See pictures on the following page.
10.5 Reagent and Waste Reservoirs

The reagent and waste reservoirs are Duran type glass bottles provided with lids that are pre-fitted with tubing, connectors and PTFE/Nylon filters as appropriate. Assembled bottles are shown below.

Each reservoir bottle, lid and connected line is marked and located on the instrument as outlined in Table 3 below. Before performing any operation on the Parsortix PC1 instrument, the user must ensure that the following amounts of reagents are in place:

- Waste reservoir bottle must contain <400mL of liquid;
- Buffer reservoir bottle must contain >100mL PBS;
- Cleaning reservoir must contain >50mL 10% ProKlenz 120 solution;
- Priming reservoir must contain >10mL 100% (absolute) ethanol.

When removing the bottles, it is advised that the user 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 during bottle changes.

Table 3. Parsortix PC1 Instrument Reagent and Waste Bottle Identification.

<table>
<thead>
<tr>
<th>Reservoir</th>
<th>Bottle volume</th>
<th>Line ID</th>
<th>Position on instrument</th>
<th>Connection port</th>
<th>Required Reagent</th>
</tr>
</thead>
<tbody>
<tr>
<td>Waste</td>
<td>500mL</td>
<td>W</td>
<td>Left bay</td>
<td>Left and middle</td>
<td>Undiluted Sodium Hypochlorite bleach (50 ml)</td>
</tr>
<tr>
<td>Buffer</td>
<td>250mL</td>
<td>B</td>
<td>Left bay</td>
<td>Right</td>
<td>PBS buffer</td>
</tr>
<tr>
<td>Priming reagent</td>
<td>100mL</td>
<td>P</td>
<td>Right bay</td>
<td>Left</td>
<td>Absolute Ethanol</td>
</tr>
<tr>
<td>Cleaning reagent</td>
<td>250mL</td>
<td>C</td>
<td>Right bay</td>
<td>Right</td>
<td>10% ProKlenz solution</td>
</tr>
</tbody>
</table>
10.5.1 Waste Reservoir Replacement

- Firmly hold the lid connected to the waste reservoir and carefully unscrew the bottle by rotating it in a clockwise direction. Holding the lid stationary will prevent kinking of the tubing connected to the lid during bottle changes.

- Appropriately dispose of the contents inside the waste reservoir bottle and place the bottle aside for cleaning.

- Wipe the lines attached to the lid with an alcohol-soaked wipe.

- Use 50 ml undiluted solution of Sodium Hypochlorite to a clean 500mL Duran type bottle (Empty reservoir when the waste volume reaches 400 ml and replace 50 ml of disinfectant)

- Firmly hold the waste reservoir lid and carefully screw the new waste reservoir bottle containing the Sodium Hypochlorite solution onto the lid by rotating the bottle in a counter-clockwise direction.

10.5.2 Buffer Reservoir Replenishment or Replacement

Follow these steps if the buffer reservoir requires filling or when the buffer reservoir needs to be replaced for the purposes of the weekly maintenance procedure:

- Firmly hold the lid connected to the buffer reservoir and carefully unscrew the bottle by rotating it in a clockwise direction. Holding the lid stationary will prevent kinking of the tubing connected to the lid during bottle changes.

- Wipe the line attached to the lid with an alcohol-soaked wipe.

- If the buffer reservoir requires filling, add the appropriate amount of PBS buffer to the bottle. If the buffer reservoir requires replacement (i.e. for the weekly maintenance procedure), obtain a clean 250mL Duran type bottle and fill with 250mL of PBS buffer.

- Firmly hold the buffer reservoir lid and carefully screw the filled buffer reservoir bottle onto the lid by rotating the bottle in a counter-clockwise direction.

- Run the PX2_LOAD protocol to remove any air potentially introduced by the removal of the lid from the buffer reservoir by doing the following:
  
  o Select the "PX2_LOAD" protocol using the instrument control panel;
  
  o Press [Run] then [Start];
  
  o When prompted, "Waste empty?", ensure that the waste reservoir (500mL bottle connected to the line labelled "W") has <400mL of liquid. If the level of the waste fluid is ≥400mL, change the waste reservoir as detailed above in Section 10.5.1. Press [OK].
  
  o When prompted “Finished LOAD” “Back to Main menu?”, press [OK] and [continue] to return to the main screen;
  
  o Ensure that the waste reservoir (500mL bottle connected to the line labelled "W") has <400mL of liquid. If the level of the waste fluid is ≥400mL, change the waste reservoir as detailed above in Section 10.5.1.

10.5.3 Priming Reservoir Replenishment or Replacement

- Firmly hold the lid connected to the priming reservoir and carefully unscrew the bottle by rotating it in a clockwise direction. Holding the lid stationary will prevent kinking of the tubing connected to the lid during bottle changes.
• Wipe the line attached to the lid with an alcohol-soaked wipe.

• If the priming reservoir requires filling, add the appropriate amount of 100% (absolute) ethanol to the bottle. If the priming reservoir requires replacement (i.e. for the weekly maintenance procedure), obtain a clean 100mL Duran type bottle and fill with 100mL of 100% (absolute) ethanol.

• Firmly hold the priming reservoir lid and carefully screw the filled priming reservoir bottle onto the lid by rotating the bottle in a counter-clockwise direction.

10.5.4 Cleaning Reservoir Replenishment or Replacement

• Firmly hold the lid connected to the cleaning reservoir and carefully unscrew the bottle by rotating it in a clockwise direction. Holding the lid stationary will prevent kinking of the tubing connected to the lid during bottle changes.

• Wipe the line attached to the lid with an alcohol-soaked wipe.

• If the cleaning reservoir requires filling, add the appropriate amount of 10% Proklenz solution (prepared as described in Section 10.3) to the bottle. If the cleaning reservoir requires replacement (i.e. for the weekly maintenance procedure), obtain a clean 250mL Duran type bottle and fill with freshly prepared 10% Proklenz solution (prepared as described in Section 10.3).

• Firmly hold the cleaning reservoir lid and carefully screw the filled cleaning reservoir bottle onto the lid by rotating the bottle in a counter-clockwise direction.

10.6 Harvest Valve Operation

As part of the normal operation of the Parsortix PC1 instrument, the user is required to manually rotate the Harvest valve between two set positions called “SEP” and “HAR”.

The default position for the valve is the “SEP” position as indicated below. The valve must remain in the “SEP” position for all of the protocols (i.e. PX2_LOAD, PX2_PRIMING, PX2_CLEAN and the separation protocol MBC01), unless otherwise instructed.
The alternative position is the “HAR” position, which should only be used when prompted by the instrument at specific points during the execution of the MBC01 protocol. This position is shown below.

10.7 Operating Protocols Overview
The Parsortix PC1 instrument is operated through specific, programmable instructions in a proprietary format, called Protocols. There are four protocols installed on the instrument at the time of installation to facilitate system operation for the desired intended use:

- **PX2_CLEAN**: Protocol to enable the instrument to be cleaned prior to use. This protocol is supplied to support documented regular cleaning and weekly maintenance procedures (see Section 10.8.2 and Section 10.9, respectively).
- **PX2_LOAD**: Protocol used to purge the system of air when the buffer reagent reservoir has been replenished or replaced. This protocol is supplied to support reagent replenishment/replacement and weekly maintenance procedures (see Section 10.5 and Section 10.9, respectively).
- **PX2_PRIMING**: Protocol to enable the instrument to be primed (flowpath filled with liquid with all air removed). This protocol is supplied to support the documented weekly maintenance procedure (see Section 10.9).
- **MBC01**: Protocol used to perform the core cell separation and harvest function of the instrument as described in the PC1 CE-OM-B Parsortix PC1 Instrument CE Instructions for Use and MBC CE-OM-C Parsortix PC1 CE MBC-01 Metastatic Breast Cancer Kit Instructions for Use documents. The protocol contains a sequence of instructions for priming, performing sample separation and harvest, and automatically cleaning the instrument with minimal user intervention. The instrument is left in a state ready to process another sample immediately once MBC01 has completed.

10.8 Routine Maintenance Procedures
10.8.1 Prior to Instrument Operation
To maintain instrument cleanliness and minimize the risk of cross contamination between samples, the following steps must be performed before every instrument operation:

- Visually inspect the instrument for any signs of kinks, leaks, or damage.
• Ensure that a clean 50mL Falcon tube is attached to the sample mount of the Parsortix PC1 instrument.

• Ensure the harvest waste line “H” is plugged into the cap of the harvest waste tube.

• Ensure harvest waste tube (50mL Falcon tube) attached to the harvest line contains <25mL fluid. If it contains >25mL of fluid, remove the old tube, wipe the harvest line with an alcohol wipe, and attach a clean, empty 50mL Falcon tube.

• Ensure a GEN3C cleaning cassette is inside the clamp assembly.

• Ensure the harvest valve is turned clockwise to the “SEP” position.

• Check the level and expiration date of the reagents to ensure that all are fresh (e.g. not expired) and that the reservoirs are filled prior to operation.

<table>
<thead>
<tr>
<th>Reagent / Reservoir</th>
<th>Bottle Size</th>
<th>Line</th>
<th>Refill/Empty at</th>
<th>Refill to</th>
</tr>
</thead>
<tbody>
<tr>
<td>PBS Buffer</td>
<td>250mL</td>
<td>“B”</td>
<td>≤100mL</td>
<td>250mL</td>
</tr>
<tr>
<td>Approved Reagents:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>PBS Without Ca+ &amp; Mg+</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Waste Reservoir</td>
<td>500mL</td>
<td>“W”</td>
<td>≥400mL</td>
<td></td>
</tr>
<tr>
<td>Approved Reagents:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Undiluted Sodium Hypochlorite (50 ml) for clean Waste Container</td>
<td></td>
<td></td>
<td></td>
<td>Empty reservoir when the waste volume reaches 400 ml and replace 50 ml of disinfectant</td>
</tr>
<tr>
<td>Cleaning Solution</td>
<td>250mL</td>
<td>“C”</td>
<td>≤50mL</td>
<td>250mL</td>
</tr>
<tr>
<td>Approved Reagents:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Error! Reference source not found.</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Priming Solution</td>
<td>100mL</td>
<td>“P”</td>
<td>≤10mL</td>
<td>≥50mL</td>
</tr>
<tr>
<td>Approved Reagents:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>100% Ethanol</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

If any of the reagents are expired or if the waste reservoir is full, remove the currently attached bottles and replace with clean bottles containing the appropriate volume of fresh reagents (with new expiration dates as applicable) as described in Section 10.5 above.

10.8.2 Instrument Cleaning
The Parsortix PC1 instrument must have been cleaned in the previous 24 hours before processing a sample (either by running the MBC01 or PX2_CLEAN protocols). If the instrument has not been used for more than 24 hours, run the PX2_CLEAN protocol prior to using the instrument for sample processing as follows:

• Ensure that an empty 50mL Falcon tube is attached to the sample mount.

• Select the “PX2_CLEAN” protocol on the instrument control panel.

• Press [Run] then [Start].

• When prompted “Insert Cleaning Cass”, confirm that the current cleaning cassette is inserted in the clamp. Press [OK].

• When prompted “50mL ProKlenz?”, verify cleaning reservoir bottle (250mL bottle connected to line labelled “C”) contains >50mL 10% ProKlenz detergent and press [OK].
• When prompted “100mL Buffer?”, verify buffer reservoir bottle (250mL bottle connected to line labelled “B”) contains >100mL PBS and press [OK].

• When prompted “Waste empty?”, ensure the waste reservoir bottle (500mL bottle connected to line labelled “W”) has <400mL of liquid. Press [OK].

• The instrument will run for ~45 minutes. When prompted “Remove Vacutainer”, remove the 50mL Falcon tube from sample mount and press [OK].

• When prompted “Clean Vacutainer-Line”, wipe the sample line with an alcohol-soaked wipe and press [OK].

• When prompted “Attach New Vacutainer”, attach a clean 50mL Falcon tube to the sample mount and press [OK].

• When prompted “Finished CLEAN” “Back to Main Menu”, press [OK].

• When prompted “Protocol Finished”, press [continue].

• Check reagent levels as described above in Section 10.8.1.

10.9 Weekly Maintenance Procedure

In order to maintain instrument cleanliness and ensure optimal performance, the below weekly maintenance procedure must be adhered to. It is critical that all steps and actions set out in this section are followed. It is recommended that the weekly maintenance procedure always be performed on the same day of the week. All bottles removed from the instrument should be emptied and washed or autoclaved prior to refilling and reuse on the instrument.

The weekly maintenance procedure detailed below will take approximately 3 hours to complete.

10.9.1 Reagent Replacement

• Ensure that a clean 50mL Falcon tube is attached to the sample mount.

• Remove and replace the waste reservoir bottle (500mL bottle connected to line labelled “W”) as described in Section 10.5.1.

• Remove and replace the buffer reservoir bottle (250mL bottle connected to line labelled “B”) as described in Section 10.5.2.

• Remove and replace the priming reservoir bottle (100mL bottle connected to line labelled “P”) as described in Section 10.5.3.

• Remove and replace the cleaning reservoir bottle (250mL bottle connected to line labelled “C”) as described in Section 10.5.4.

• Carefully remove and discard the harvest waste tube (50mL Falcon tube attached to the Harvest line), wipe the line with an alcohol wipe, and attach a new 50mL Falcon tube.

• Check that the connectors for all four of the reservoir bottles (both at the instrument bulkhead and on the respective reservoir lids) are tight by turning each connector clockwise until the connectors click.

• Check that there are no visible leaks around the instrument, in particular at the cassette clamp. If leaks are observed, contact ANGLE Technical Support.
• 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 replacement O-rings provided.

• Check that the filters on the buffer, waste, cleaning, and priming reservoirs are in place, and there is no noticeable contamination or damage. If the filters appear to be damaged or contaminated, replace them with the appropriate replacement filters provided.

• Check that the external tubing, especially the tubing connecting the instrument to the cassette clamp, are not kinked or visibly blocked.

• Clean the external cover of the instrument with an alcohol-soaked wipe.

10.9.2 New Cleaning Cassette Preparation

• Ensure that the previous GEN3C cleaning cassette is still inserted in the cassette clamp of the instrument.

• Obtain a new Parsortix PC1 GEN3C cleaning cassette and label the cassette as “Cleaning” with the appropriate expiration date (7 days from the current date).

• Select the “PX2_PRIMING” protocol on the instrument.

• Press [Run] then [Start].

• When prompted “100mL Buffer?”, verify buffer reservoir bottle (250mL bottle connected to the line labelled “B”) contains >100 mL PBS and press [OK].

• When prompted “10mL EtOH?”, verify priming reservoir bottle (100mL bottle connected to the line labelled “P”) contains >10mL Absolute ethanol and press [OK].

• When prompted “Waste Empty?”, verify waste reservoir bottle (500mL bottle connected to the line labelled “W”) contains <400mL liquid and press [OK].

• The instrument will run for ~4 minutes. When prompted to “Insert new cassette”, remove the old cleaning cassette from the clamp and properly dispose of it.

• Insert the new properly labelled cleaning cassette into the cassette clamp and close the clamp. Press [OK]. The instrument will run for another ~7 minutes.

• When prompted “Finished PRIMING”, press [OK] and [continue] to return to the main screen.

The new cleaning cassette can stay inside the clamp until the next time the Parsortix PC1 instrument is used. A cleaning cassette can be used for up to 7 days after its initial priming or after up to 10 blood separations, whichever comes first.

10.9.3 Process ICT Sample

Following the maintenance described above, an Instrument Control Test (ICT) must be performed. Refer to ICT CE-OM-C Parsortix PC1 CE ICT01 Instrument Control Test Kit Instructions for Use for full details.

• If the ICT results fail, run the PX2_CLEAN protocol (Section 10.8.2) and repeat the ICT procedure.

• If the ICT results fail for the second time on the cleaned instrument, contact the ANGLE Technical Support team. No further work should be conducted using a Parsortix PC1 instrument that has not passed an ICT.
10.9.4 Preventive Maintenance Procedures
Further regular maintenance procedures should be carried out by ANGLE staff at quarterly and yearly intervals. Contact ANGLE Technical Support for further information.

11. Troubleshooting
The following table describes the recommended actions for instrument users to address problems during the operation of the Parsortix PC1 instrument. Contact ANGLE Technical Support if further advice is required, problems persist, or kinks, leaks or other damage is observed.

<table>
<thead>
<tr>
<th>Problem</th>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>The instrument does not switch on.</td>
<td>1. Check the electrical supply to the lab.</td>
</tr>
<tr>
<td></td>
<td>2. Check that the instrument is connected to the power outlet and the power supply unit is connected to the instrument.</td>
</tr>
<tr>
<td></td>
<td>3. Disconnect the power supply from the power outlet for 15 seconds and then reconnect the power supply to the power outlet. Then turn on the instrument.</td>
</tr>
<tr>
<td></td>
<td>4. If the instrument does not turn on, power off the instrument.</td>
</tr>
<tr>
<td></td>
<td>5. Inspect the fuse holder and the supply fuse located on the left-hand side of the instrument. Replace if necessary.</td>
</tr>
<tr>
<td></td>
<td>6. If none of the steps above solve the problem, contact ANGLE Technical Support</td>
</tr>
<tr>
<td>The instrument is unresponsive to key presses, or the main screen is blank.</td>
<td>1. Switch the instrument off and on again and observe the message “Parsortix system starting” on the main screen.</td>
</tr>
<tr>
<td></td>
<td>2. Once the instrument is responsive, run a PX2_CLEAN before resuming normal operations.</td>
</tr>
<tr>
<td></td>
<td>3. If the problem persists, contact ANGLE Technical Support</td>
</tr>
<tr>
<td>Unable to select protocols on the main screen.</td>
<td>1. Switch the instrument off and on again and observe the message “Parsortix system starting” on the main screen.</td>
</tr>
<tr>
<td></td>
<td>2. If the problem persists, contact ANGLE Technical Support</td>
</tr>
<tr>
<td>Error messages on the main screen e.g., “Error loading protocols”, “Communication error,” or “Service due.”</td>
<td>1. Follow on-screen prompts where possible.</td>
</tr>
<tr>
<td></td>
<td>2. If the problem persists, contact ANGLE Technical Support</td>
</tr>
<tr>
<td>Discolorations in the buffer, priming, or cleaning reagent reservoir bottles.</td>
<td>1. Verify that only the specified reagents have been utilized.</td>
</tr>
<tr>
<td></td>
<td>2. Replace discoloured reservoir bottles (and lines if possible) with clean ones.</td>
</tr>
<tr>
<td></td>
<td>3. If the problem persists, contact ANGLE Technical Support</td>
</tr>
</tbody>
</table>
### Problem

The system stalls, the message “Waiting for pump” is displayed, and there is no fluid dripping into the waste reservoir for more than a minute.

<table>
<thead>
<tr>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Check vacutainer or Falcon tube is properly mounted to the sample mount and that the O-ring is not pinched or damaged.</td>
</tr>
<tr>
<td>2. Check that the harvest valve is fully turned to the “SEP” position.</td>
</tr>
<tr>
<td>3. Press [Abort] to return to the main screen.</td>
</tr>
<tr>
<td>4. Check that the buffer, priming reagent, and cleaning reagent lines are properly connected.</td>
</tr>
<tr>
<td>5. Ensure that the waste bottle level is below 400mL.</td>
</tr>
<tr>
<td>6. Check that the lid filters on the buffer, priming reagent, cleaning reagent, and waste bottles are dry. Replace if necessary.</td>
</tr>
<tr>
<td>7. If none of the steps above solve the problem, contact ANGLE Technical Support.</td>
</tr>
</tbody>
</table>

### Problem

The instrument is not taking up the sample

<table>
<thead>
<tr>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. If there is a continuous loud buzzing:</td>
</tr>
<tr>
<td>i. Check that the vacutainer is mounted properly.</td>
</tr>
<tr>
<td>ii. If noise continues, turn off the instrument, remove the vacutainer and inspect the mount O-rings. If the O-rings appear to be damaged, replace the O-rings.</td>
</tr>
<tr>
<td>2. Check that the harvest valve is fully turned to the “SEP” position.</td>
</tr>
<tr>
<td>3. Ensure the waste bottle level is below 400mL.</td>
</tr>
<tr>
<td>4. Tap the vacutainer to agitate the sample and observe if fluid is being taken up.</td>
</tr>
<tr>
<td>5. If none of the steps above solve the problem, this suggests a blockage in the flow path, contact ANGLE Technical Support.</td>
</tr>
</tbody>
</table>

### 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. Properly clean the instrument and the surrounding area. Refer to the PC1 User’s Manual for additional information.

<table>
<thead>
<tr>
<th>Solution</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Check and tighten all connections (depending on leak position).</td>
</tr>
<tr>
<td>2. Check all lines for visual damage (depending on leak position); If lines are damaged, please contact ANGLE Technical Support.</td>
</tr>
<tr>
<td>3. Check the cassette for visible damage.</td>
</tr>
<tr>
<td>4. Ensure that the cassette is inserted correctly in the clamp.</td>
</tr>
<tr>
<td>5. Check waste and other fluids levels. Empty or fill, as necessary.</td>
</tr>
<tr>
<td>6. Check the harvest waste tube level and empty if necessary.</td>
</tr>
<tr>
<td>7. Remove the sample tube and check the O-rings for visible damage. If the O-rings appear to be damaged, replace the O-rings.</td>
</tr>
<tr>
<td>8. Check if the vacutainer contains more than 10mL of fluid; If the Vacutainer contains &gt;10mL of fluid, please contact ANGLE Technical Support.</td>
</tr>
<tr>
<td>9. Perform a CLEAN.</td>
</tr>
<tr>
<td>10. If the problem persists, contact ANGLE Technical Support.</td>
</tr>
</tbody>
</table>
11.1 Standard Recovery Procedure

The standard recovery procedure safely shuts down and restarts the Parsortix PC1 instrument.

- If needed, return to the main menu by pressing and holding [Abort] then [Continue].
- Switch off the instrument by pressing [System] then [Shutdown]. When prompted, “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 of the instrument.
- After 15 seconds, switch the instrument on using the main ON/OFF switch.
- Run a cleaning cycle by selecting “PX2_CLEAN” and press [Run] then [Start]. Follow the instructions for the cleaning process in Section 10.8.2.
- After the cleaning cycle has finished, return to the main menu and run an ICT sample (see ICT-CE-OM-A Parsortix PC1 CE ICT-01 Instrument Control Test Kit Instructions for Use).
  - If the ICT sample fails, immediately stop using the instrument and contact ANGLE Technical Support.
  - If the ICT sample succeeds but the problem persists, stop using the instrument and contact ANGLE Technical Support.
  - If the ICT sample succeeds and the problem is solved, continue using the instrument.
12. **Technical specifications**

Supply voltage: 110V/240V automatically adjustable AC 50/60Hz input 24 V DC 4.16 A output

Fuse rating: 3.15 A Fast 20 mm

The Parsortix PC1 instrument has been tested in accordance with the following electrical safety standards:

- UL 61010-1:2012 /R:2016-04
- CAN / CSA C22.2 No. 61010-1: 2012/U2:2016-04

12.1 **Symbols Used**

The Parsortix PC1 instrument carries the following operational labels:

<table>
<thead>
<tr>
<th>SYMBOL</th>
<th>MEANING</th>
</tr>
</thead>
<tbody>
<tr>
<td><img src="image" alt="i" /></td>
<td>READ INSTRUCTIONS</td>
</tr>
<tr>
<td><img src="image" alt="ce" /></td>
<td>CE Mark</td>
</tr>
<tr>
<td><img src="image" alt="biohazard" /></td>
<td>BIOHAZARD</td>
</tr>
<tr>
<td><img src="image" alt="manufacturer" /></td>
<td>MANUFACTURER</td>
</tr>
<tr>
<td><img src="image" alt="caution" /></td>
<td>CAUTION</td>
</tr>
<tr>
<td><img src="image" alt="weee" /></td>
<td>WEEE</td>
</tr>
<tr>
<td><img src="image" alt="serial_number" /></td>
<td>SERIAL NUMBER</td>
</tr>
<tr>
<td><img src="image" alt="fragile" /></td>
<td>FRAGILE</td>
</tr>
<tr>
<td>Term</td>
<td>Description</td>
</tr>
<tr>
<td>----------------------</td>
<td>---------------------------------------------------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>DIRECT CURRENT</td>
<td>Indicates direct current supply to the equipment.</td>
</tr>
<tr>
<td>FUSE</td>
<td>Location, value and characteristics of the external system fuse.</td>
</tr>
<tr>
<td>THIS WAY UP</td>
<td>Preferred packaging orientation for storage and shipping.</td>
</tr>
<tr>
<td>KEEP DRY</td>
<td>Packaging should be kept dry at all times during storage and shipping.</td>
</tr>
<tr>
<td>HARVEST/SEPARATE</td>
<td>A switchable valve to select cell separation or cell harvesting mode.</td>
</tr>
<tr>
<td>NOTIFIED BODY SYMBOL</td>
<td>The product has been safety tested by TÜV for conformity to IEC 61010-1 or equivalent standards for markets including EU, USA and Canada.</td>
</tr>
<tr>
<td>IN VITRO DIAGNOSTIC DEVICE</td>
<td>The device is designated as an In Vitro Diagnostic Device and is for in vitro diagnostic use in accordance with the intended use statement</td>
</tr>
<tr>
<td>Rx ONLY</td>
<td>Prescription only – United States Federal law restricts this device to sale by or on the order of a physician or other practitioner licensed by the law of the State in which he/she practices to use, or order the use of, the device.</td>
</tr>
<tr>
<td>CATALOG NUMBER</td>
<td>Indicates the manufacturer's catalogue number of the device to aid identification.</td>
</tr>
<tr>
<td>EC REP</td>
<td>Indicates the European Union Authorised Representative for the Parsortix system.</td>
</tr>
</tbody>
</table>
12.2 Material Compatibility

The Parsortix PC1 instrument has been assessed for compatibility with a range of known reagents as listed in Table 4.

Table 4. List of compatible chemicals and reagents.

<table>
<thead>
<tr>
<th>Chemical/Reagent</th>
</tr>
</thead>
<tbody>
<tr>
<td>1x PBS without Ca$^{2+}$/Mg$^{2+}$</td>
</tr>
<tr>
<td>70-100% Ethanol</td>
</tr>
<tr>
<td>Distilled water</td>
</tr>
<tr>
<td>10% ProKlenz® 120 Detergent</td>
</tr>
<tr>
<td>1% BSA 2mM EDTA in PBS buffer without Ca$^{2+}$/Mg$^{2+}$</td>
</tr>
</tbody>
</table>

For assessment of the instrument compatibility with chemicals and reagents that are not on this list, please contact ANGLE Technical Support prior to use.

12.3 Disposal of electronic equipment and accessories

At the end of life, the Parsortix PC1 instrument must be cleaned by performing a cleaning procedure using PX2_CLEAN (see Section 10.8.2) before disposal according to local waste recycling regulations or return it to ANGLE. Unused or expired cassettes can be disposed in general waste disposal.

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 ANGLE Technical Support 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.

Please contact an ANGLE Technical Support 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.
13. **Technical support**

Contact ANGLE Technical Support if further advice is required.

Device manufacturer:

**ANGLE Europe Ltd**
10 Nugent Road
Surrey Research Park
Guildford, Surrey
GU2 7AF
United Kingdom
Tel: +44 (0) 1483 343434
Email: eu-support@angleplc.com
www.angleplc.com

Authorised manufacturer’s representative in the European Union:

**Medical Device Management Ltd**
Block B, The Crescent Building, Northwood,
Santry Dublin 9,
D09 C6X8, Ireland
Tel: +353 (0) 1893 4143
Email: eu-repmail@meddevman.onmicrosoft.com
http://www.medicaldevicemanagement.com/

Authorised manufacturer’s representative in North America:

**ANGLE North America Inc**
5100 Campus Drive
Suite 120
Plymouth Meeting, PA 19462
Email: us-support@angleplc.com
www.angleplc.com