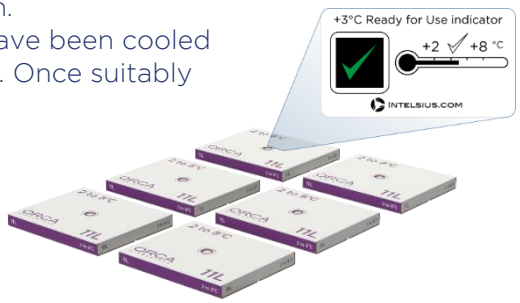
ORCA Single-Use 2 to 8°C Conditioning Guides

FREEZER TO ROOM TEMPERATURE PREPARATION

-18°C

1. Place the ORCA Single-Use cassettes into a freezer and allow sufficient time for the cassettes to completely freeze (suggested minimum time of 24hrs at a warmest temperature of -18°C). These should be spaced out in the controlled freezer space until completely frozen. Ensure all parts of all ORCA Single-Use cassettes have been cooled such that the cassettes are frozen solid throughout. Once suitably frozen the cassettes can be held in the freezer space until the ORCA systems are ready to use.



+20°C

2. Take the frozen ORCA Single-Use cassettes from the freezer space and lay the cassettes in a room temperature environment (+20°C +/- 5°C). Ensure they are well spaced with sufficient airflow over the labelled face. The cassettes require a minimum time of 90 minutes at this temperature in this space before they are ready for use.

The ideal temperature for packing is +4.5C +/- 0.5°C. The temperature of the cassette can be checked using a surface probe in the aperture on the cassette. If the temperature is above +5.5°C, the performance will suffer. If the temperature is below +4°C, then there is a risk of cold shocking the payload. We recommend if the surface temperature of the cassettes is above +4°C at any time during this period restart preparation from 1. If the surface temperature of the cassette is above +5.5°C at any time during this period preparation must be restarted from 1.

3. The ORCA Single-Use cassettes define a fixed payload space where temperature control is maintained. Place one PCM cassette in the base of the ORCA Single Use system, with the coloured side running left to right. Pack two PCM cassettes, one at the front and one at the back, with the shortest side resting on the base of the VIP panel and the coloured sides running vertically. Pack a further two PCM cassettes against the sides of the ORCA Single Use insulation, one on each side, with the longest side resting on the base cassette and the coloured sides running front to back. The payload can now be inserted into the space defined by these 5 cassettes. Place the remaining PCM cassette flat on top, this cassette should rest on the left and right cassettes with the coloured sides running left to right.

4. Close the outer case lid, secure the fasteners and seal with three strips of packing tape following the tape area marked with dotted lines. The ORCA is now ready to be shipped.

NOTICE

Do not puncture, scratch or bend the white vacuum insulation panels. This may result in vacuum loss, which will significantly reduce system performance. Each panel should feel rigid and have a tense surface. If the vacuum has been lost panels will feel soft, flaccid and have a loose-fitting surface.

If you believe any panel has been damaged do not use this system and refer to your local SOP or your Intelsius representative for guidance.

Intelsius recommend that customers conduct validation work of the preparation guidelines based on specific equipment, processes and ambient environment in line with Good Distribution Practices (GDP).

For alternative preparation protocols please contact *compliance@intelsius.com*