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AMERCARE
PROTECTING YOUR PRODUCT AND ENVIRONMENT

Amercare Product Specification

Isolator Product Code
A2/CIN23B

Version:- 12 Rev 01

Product Specification for AMERCARE ISOLATOR

Version: Amercare Isolator Specification v12

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Introduction

This specification describes the Amercare A2 Isolator System, used for the safe aseptic reconstitution and preparation of both hazardous and non-hazardous sterile products. These operations can be performed in a European Grade A environment which is leak testable, easily maintained and sterilised, whilst protecting the operator from exposure to hazardous material.

Contents

Terms

AHU	Air Handling Unit	OQ	Operational Qualification
cfm	Cubic Feet per Minute	P&ID	Process and Instrumentation Drawing
DOP	Dispersed Oil Particulate	Pa	Pascals
DQ	Design Qualification	PoE	Power Over Ethernet
FQT	Factory Qualification Testing	PTZ	Pan, Tilt, Zoom
HEPA	High Efficiency Particulate Air	SOP	Standard Operating Procedure
LED	Light Emitting Diode	UPS	Uninterruptable Power Supply
O&M	Operation and Maintenance	URS	User Requirement Specification
		VMP	Validation Master Plan

1 General Description

1.1 Main chamber

1.1.1 The main chamber is constructed from grade 316 stainless steel, the surface is unpainted, and bead blasted to a smooth satin finish. All internal surfaces are continuous and easy to clean.

1.1.2 The working zone of the main chamber is 550mm deep and the upper part of the back wall is angled at 45° to allow the operator to reach all surfaces for cleaning. The width of the chamber depends on the number of glove ports specified by the customer. The sizes of the standard range of isolators are given in the table at the rear of this specification.

1.1.3 The turbulent air is distributed by two specially designed diffuser heads which can be easily removed for cleaning. The main chamber is provided with a test point to enable air sampling.

1.1.4 A LED tube light unit (for each working position) is fitted externally to the main chamber and provides lighting levels of approximately 1000 lux at the work surface. The light unit is positioned in such a way as to reduce reflections and glare.

1.1.5 A single fused electrical socket rated at 6 Amps is fitted into the RH end wall of the main chamber. The socket is protected by an independent miniature circuit breaker and is switched from the digital alarm unit. The spur is automatically switched off in the event of a power failure. Additional sockets can be provided as an optional extra.

1.1.6 The main chamber is fitted with a fixed viewing panel secured by stainless steel pressure bars.

1.1.7 All internal surfaces are accessible for cleaning through the glove ports. The base of the Isolator is continuous, (no air grilles) and will contain any spillage.

1.1.8 The floor of the Main Chamber is supplied with a feature that allows for the fitment, external to the chamber, of a Dose Calibrator. The feature creates a leak tight interface between the Main Chamber and the Dose Calibrator. Different types Dose Calibrators can be accommodated. As standard the feature is designed for Capintec Dose Calibrators

1.1.9 Integrated into the floor of the Main Chamber is a Centrifuge. The well that forms the centrifuge is welded onto the main chamber and is finished to the same standard. See Section 11 for full details of the Centrifuge.

1.2 Transfer Chamber

1.2.1 A single transfer chamber can be situated either to the Left-hand or Right-hand side of the main chamber

1.2.2 The transfer chamber is constructed from grade 316 stainless steel, the surface is unpainted, and bead blasted to a smooth satin finish. All of the internal surfaces are continuous and easy to clean.

1.2.3 The base of the hatch is slightly higher than the main chamber which allows product to be easily passed into the main chamber without lifting. The transfer hatches are angled at 10° to the main chamber which enables the operator to reach into the transfer chamber from the glove ports easing the transfer of products into the main chamber.

1.2.4 The airflow within the transfer chamber is turbulent. Air is distributed by two specially designed diffuser heads which can be easily removed for cleaning.

1.2.5 The air grade will be return to Grade A within an absolute maximum of 2 minutes of closing the outer hatch door. The transfer hatch is provided with a test point to enable air sampling.

1.2.6 Hatch doors are manufactured from clear cast acrylic. Upon release of the vacuum seal the doors are lifted onto conveniently located pegs. The weight of the door is only 850gm to minimise the possibility of RSI and ULD.

1.2.7 The transfer hatch doors are secured and locked in place by means of a vacuum applied between two continuous silicone seals fixed to the hatch door. Operating the door close switch applies a vacuum to the space between the two seals thus securing the door to the wall of the isolator. Vacuum for the door seals is provided by a vacuum pump that is backed up via use of a UPS (Uninterruptible Power Supply). This should provide power to the vacuum pump for approximately two hours. This means that the integrity of the isolator is maintained for short periods of interruption of the mains electrical supply.

1.2.8 The transfer doors are fitted with a failsafe timed interlock which is factory set at 2 minutes. The inner door cannot be opened within 2 minutes of the outer door being closed. The time remaining to the release of the interlock is displayed on the control system and cannot be overridden.

1.3 Base Frame

1.3.1 The isolator is height adjustable and is designed so that the operator can work in either a standing or sitting position. The working height for the main process chamber can be adjusted between 750mm and 1200mm.

1.3.2 Height adjustment is by means of an electric motor with controls situated on the control module at the top of the isolator. The mechanism is contained within the base frame for ease of cleaning.

1.3.3 The main chamber and transfer chamber are supported on a base frame which has 330mm of clear unobstructed knee room.

1.3.4 A Footswitch for the inner door is mounted onto a bracket which is fixed to the adjustable base frame assembly.

2 Operating Conditions

2.1 Air Quality

2.1.1 The isolator is designed to provide clean air to EC GMP Grade A within the Process Chamber, and the transfer chamber after the clean-up period.

2.1.2 The air flow is turbulent ensuring air particles are removed throughout the Isolator System and scavenging/cleaning takes place around all contents of the Isolator.

2.1.3 During normal operation, air is drawn through each of the modules via individual inlet HEPA filters and discharged through exhaust HEPA filters.

2.1.4 HEPA filters are tested by the manufacturer to BS 3928.

2.1.5 All filters are DOP tested during the FQT. The inlet filters are again testing during OQ Testing to EN ISO 14644-3 Section B.6.2.3 to ensure that they meet the required criteria.

2.1.6 Extract line particle counts are also undertaken during OQ. This is to check that all extract filters are fitted correctly and are functioning to the required specification.

2.1.7 Where exhaust filters may become potentially contaminated from hazardous materials the filters can be removed by withdrawing into a bag located onto the filter housing to enable safe change.

2.1.8 The air change rate is given in the table at the back of this document.

2.1.9 Air inlet and extract is via diffuser heads fitted into the floor, at the rear of the Process Chamber and by entry (rear of chamber) and exit (roof of chamber) ports in the transfer chamber.

2.2 Operating Pressures

2.2.1 For Amercare Negative Pressure isolators a nominal pressure within the Main Process chamber of -250 Pascals has been adopted. This pressure is measured against the background pressure of the room the equipment is installed into

2.2.2 The adjoining chamber to the Main Process chamber will be set with a pressure of between -50 and -100 Pascals lower. This is to maintain product protection.

2.3 Breach Flows

2.3.1 For negative pressure isolators designed for both operator and product protection, in the event of a glove being completely removed an inward breach velocity of 0.7ms-1 will be maintained to ensure a high level of operator protection.

2.4 Clean-ups

2.4.1 On closing (and sealing) the outer Transfer Chamber door the air within that section will be purged and cleaned-up back to EU GMP Grade A within the two-minute interlock time. This is demonstrated as part of OQ Testing.

2.4.2 Following a breach to the Process section air within that enclosure will clean-up in less than five-minutes. This is not included as part of our standard OQ Testing.

2.5 Controlling / Adjusting Operating Conditions

2.5.1 Control dampers allow flow conditions and pressure differentials to be established and maintained in both the transfer chamber and the main process Isolator, to prevent contamination entering the controlled workspace as an inner transfer door is opened. The control dampers do not require adjustment on a daily basis and cannot be adjusted accidentally during normal operation or routine cleaning of the isolator.

2.5.2 If the unit is fitted with an onboard extract fan (Recirculating systems only) the isolator will be fitted with a speed controller. Adjustment to this will not be required on a daily basis so this will be installed behind a cover.

2.5.3 There are no onboard features / connections to adjust any remote extract fans.

2.6 Changing Gloves and Sleeves

2.6.1 The glove ports allow gauntlets to be changed without the Isolator being directly opened to the room environment. The replaced glove is passed into the enclosure for safe disposal.

2.6.2 If specified, the Amercare Easy Change Cuff system can be used to change gloves without breaching the isolator containment.

3 Monitoring and Alarm system

3.1 General Description

3.1.1 The isolator is fitted with a digital control system which is designed to continuously monitor and display the pressure within each of the isolator sections, the airflow in the chambers being monitored, the status of the transfer hatch doors together with other critical isolator functions.

3.1.2 The control system is protected by an Uninterruptible Power Supply (UPS) which provides power to the alarm system and the vacuum system for the transfer hatch doors.

3.1.3 The control unit will automatically switch off the light and the electrical socket in the main chamber in the event of a power failure.

3.1.4 The control system will log the time of any power failures, the time when power is restored and will restart the isolator when the power returns. The control system will remain in the error menu until it is reset by the operator.

3.1.5 If there is a mains power failure to the isolator the isolator will alarm continuously, and a LED will remain lit on the control pod to indicate the isolator is in backup mode.

3.1.6 The control system continuously displays the air pressure and the air change rate in the main chamber and the transfer chambers. The system will give an audible and visual error message if these readings deviate from pre-set conditions. The alarm will remain latched and cannot be reset until the isolator both returns to normal flow conditions and the alarm is accepted by the operator. The audible alarm can be muted.

3.1.7 The control system monitors the condition of the transfer hatch doors and gives a continuous display of the door status.

3.1.8 The system always monitors the condition of the door seals and the vacuum system maintaining an appropriate level of vacuum to the seals. The level of vacuum within the system can be seen via the fitted gauge. This is mounted to the isolator's lower front cover. A rapidly cycling gauge would indicate a leak within the door sealing circuits. This is most likely due to a damaged door seal or a door that has not been fitted correctly.

3.1.9 The control system controls the timed interlocks on the transfer hatch doors and shows the operator how much time remains before the inner door can be released.

The display shows a countdown in seconds from 120. When the countdown is completed the onboard sounder indicates that the interlock period is complete.

The interlock between outer and inner doors only works when passing items into the isolator (i.e. the inner door will not open for 120 seconds from when the outer door is closed and sealed).

3.1.10 The alarm system monitors the progress of the pressure hold test and displays the starting pressure, the current pressure and the pressure loss from the start of the test. When the test is completed the system indicates pass or failure. The operator is asked to accept the test results.

3.1.11 As part of the control system the isolator comes fitted with an onboard thermal printer.

This enables the users to print critical information including the Current Flow Conditions, Leak Test Results, Alarm Conditions and a complete Alarm Log of the last 256 alarm conditions.

All printed reports are headed with the Isolator Unit ID number, date and time and terminated with a signature box for acceptance.

Fan Failure, Power Failure alarms and Leak Test results are printed automatically. Other reports are printed on request.

The printer is conveniently mounted into the isolator base panel and is operated from the Isolator Control System

The printer uses thermal printing technology which means that you do not need to load ink, toner or cartridges. It accepts industry standard 57mm paper width.

The following reports can be printed:-

- Current Flow Conditions
- Fan Failure
- Power Failure
- Leak Test results
- Alarm Log of the last 256 alarms (formatted to A4 length to allow simple filing and faxing)
- Isolator parameter settings (password protected)

3.1.12 The control system can be supplied (as a cost option) with the ability to provide Volts Free signals for Mains Power Failure and probable Extract Fan failure.

These can then be connected to BMS / EMS / Monitoring Systems. See Section 11 for full details.

4 Gloves and Sleeves

The customer should specify requirements for glove port size, gloves and sleeves at the time of order. If no preference is expressed, then the isolator will be supplied with the following

Pharmacy Isolators - Latex gauntlets fitted to 200mm glove ports.

Radiopharmacy Isolators - Latex gauntlets fitted to 150mm glove ports.

Options are as follows:

4.1 Glove ports

4.1.1 150mm (6”) diameter, normally reserved for Radiopharmacy isolators where shielding acrylic is used for operator protection, port size is minimised in order to give maximum shielding protection.

4.1.2 200mm (8”) diameter, standard.

4.1.3 250mm (10”) diameter.

4.1.4 300mm (12”) diameter, only available with vinyl sleeves.

4.2 Gauntlets

4.2.1 Latex Gauntlets (standard) are available in a range of sizes and can fit either 150mm or 200mm diameter glove ports.

4.2.2 Neoprene Gauntlets (cost option) are available in a range of sizes and can fit either 150mm or 200mm diameter glove ports.

4.3 Sleeves

4.3.1 Latex sleeves are available to suit either a simple four ring Oval cuff or the Easy Change cuff system and can fit either 150mm or 200mm diameter glove ports.

4.3.2 Hypalon sleeves are available to suit either a simple four ring Oval cuff or the Easy Change cuff system and can fit glove ports up to 250mm diameter.

4.3.3 PVC sleeves are available to fit 200mm, 250mm, or 300mm diameter glove ports, and to suit either a simple four ring Oval cuff or the Easy Change cuff system.

4.4 Cuff Systems

4.4.1 A 4 ring Oval cuff system can be supplied at additional cost, provided that it is specified at the time of order. The cuff ring will suit a wide range of sizes of any beaded glove.

4.4.2 The Easy Change cuff system can be provided at additional cost. A separate data sheet is available to show the operation and benefits of the Easy Change system.

4.4.3 A variant of the Easy Change cuff system can be provided (at additional cost) to allow an ELS style Glove to be used.

5 Materials of Construction

The main chamber and the transfer chambers are fabricated from 3mm thick, grade 316L stainless steel sheet.

This is suitable for gaseous disinfection or sterilisation.

Other components are manufactured from corrosion resistant materials suitable for the application.

In more detail the following materials are used:-

5.1 Main Process Chamber and Transfer Chambers

5.1.1 Fully welded construction from 3mm thick grade 316L stainless steel.

5.1.2 All accessible welds are fillet welds smoothed and finished to allow ease of cleaning.

5.1.3 After fabrication the carcase is glass bead blasted to provide a smooth, glare free finish which is easy to clean and maintain.

5.2 Front Panel and Transfer Hatch Doors

5.2.1 Glove Port panels are manufactured, as standard, from 12mm thick Clear cast acrylic.

5.2.2 Glove Port panels are also available in four different thicknesses of Lead Acrylic (Premac®). These are a cost option.

5.2.3 Transfer Hatch doors are manufactured from 5mm thick Clear cast acrylic.

5.3 Internal Plastics

5.3.1 Machined Acrylic

5.3.2 Machined Acetal

5.3.3 3D Printed ABS

5.4 Door and Front Panel Seals

5.4.1 Extruded silicone rubber

5.5 Base Frame

5.5.1 The base frame is manufactured from aluminium extrusion with clear anodised finish.

5.5.2 External covers are manufactured from sheet aluminium finished in white powder coating.

5.6 External Plastics

5.6.1 Machined Acrylic
5.6.2 Machined Acetal
5.6.3 Machined / Fabricated PVC
5.6.4 3D Printed ABS
5.6.5 Vacuum formed ABS

5.7 Wheels and castors

5.7.1 Stainless Steel
5.7.2 Wheel running surface Nylon

5.8 Fixings and Fastenings

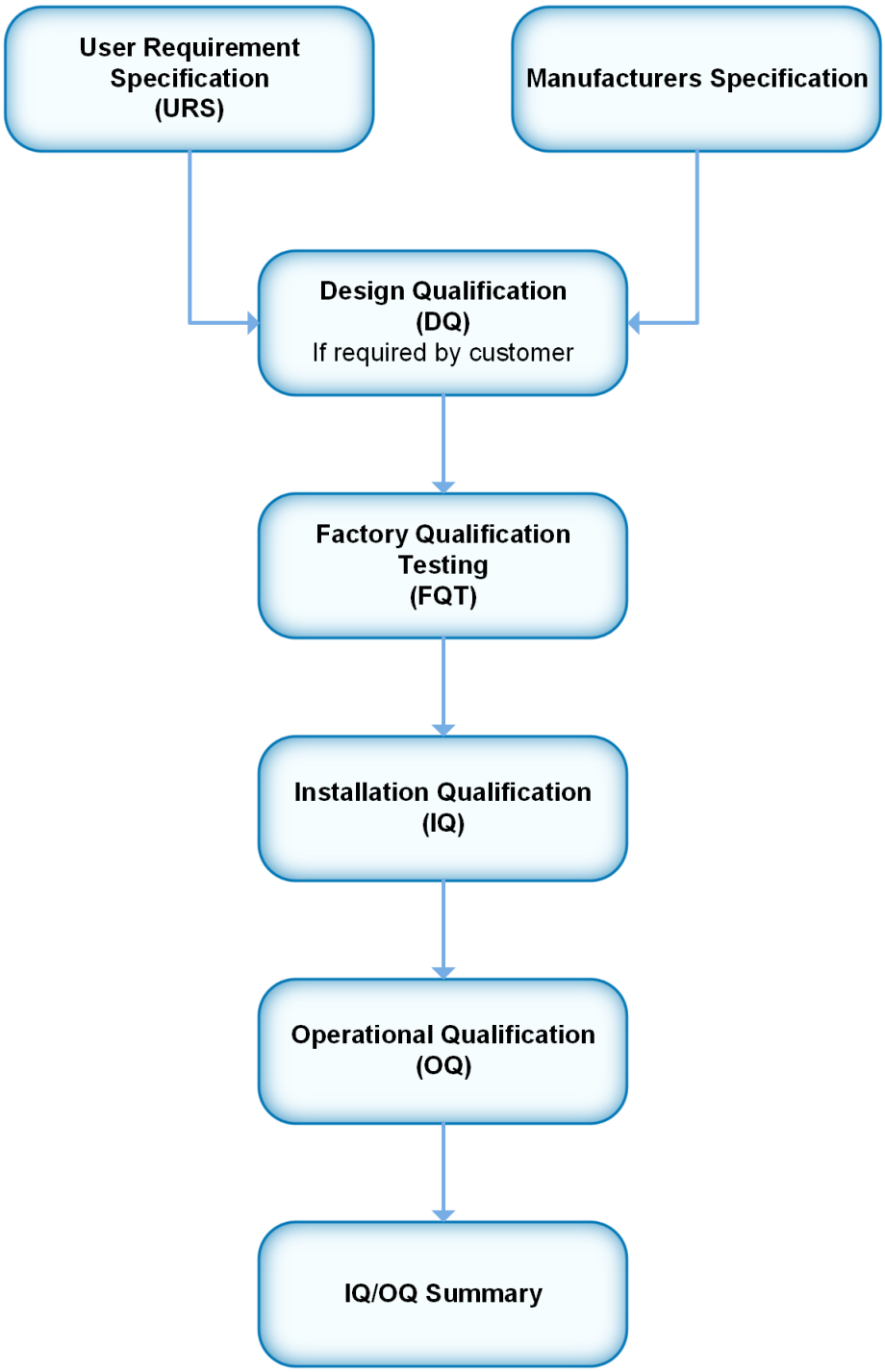
5.8.1 Stainless Steel

5.9 Connection Flexible Ductwork

5.9.1 Flexible PVC with fully encased wire reinforcement.

6 Validation of Design, Construction and Installation

All Amercare isolators are designed, constructed and tested to the following Validation Master Plan (VMP)



6.1 Specification

6.1.1 All isolators quoted for are quoted against either our Standard Specification or the customers User Requirement Specification (URS).

6.1.2 When responding to a formal tendering process a document will be produced whereby Amercare's responses to all line items within the URS for the project are responded to fully.

6.2 Design Validation

6.2.1 A Design Qualification should be carried out between Amercare and the customer. This should ideally be completed before any components for the isolator in question are ordered.

The DQ process becomes more important the further away from a standard specification of isolator that is required.

This ensures that both parties are confident that the equipment that will be supplied meets for the performance and usability requirements.

6.3 Factory Qualification

All Amercare isolators are subjected to full Factory Qualification Testing (FQT) prior to their delivery to site.

FQT's may be witnessed by the customer (or their representative) if required.

The following tests are carried out during an FQT

- Record Critical Part Serial Numbers
- Electrical Function
- Lighting Level
- Door Vacuum System & Interlock Controls
- Calibrate Pressure Transducers
- Calibrate Pressure Transducer(s)
- Function of Pressure & Flow Monitoring
- Stressing Pressure Decay Testing
- Aerosol Challenge (DOP) Testing – Inlet & Extract Filters
- Setting & Recording of Alarm Parameters

Following the above testing all isolators are electrically tested by an outside contractor and issued with Minor Electrical Installation Works Certificate.

6.4 Installation and Operational Qualification

Following their delivery to site (and any reassembly work that may be required) all isolators are subjected to Installation Qualification (IQ) and Operational Qualification (OQ) Testing.

These tests may be witnessed by the customer (or their representative) if required.

6.4.1 Installation Qualification (IQ)

The following tests are carried out during an IQ

- Documentation Review
- Installation Checklist
- Electrical Safety

6.4.2 Operational Qualification (OQ)

The following tests are carried out during OQ Testing

- Electrical Function
- Lighting Level
- Sound Level
- Door Vacuum System
- Calibrate Pressure Transducers
- Calibrate Pressure Transducer(s)
- Setting of Operating & Differential Pressures
- Function of Pressure & Flow Monitoring
- Particle Counting – Isolator Sections & Transfer Chamber Clean-ups
- Extract Line Particle Counts
- Glove Port Breach Velocities (-ve units only)
- Classification Leak Testing
- Aerosol Challenge (DOP) Testing – Inlet Filters
- Final System Checks

Sample copies of the standard Qualification Documentation package are supplied as part of any tender / enquiry response.

7 Validation and QC Testing

7.1 Test Points

7.1.1 Both the transfer chamber and the process chamber are fitted with test points for monitoring and validation.

7.1.2 Test points are also provided, on all filters, for filter validation (DOP Testing).

7.2 Leak Testing

7.2.1 Isolator leak Classification is demonstrated by means of a semi-automated pressure hold test which is simple to carry out.

7.2.2 Negative Pressure isolators are classified as Class 2 (ISO 14644-7) which is equivalent to an hourly leak rate of 2.5×10^{-3}.

7.2.3 The standard decay test for a Class 2 isolator is a pressure change of less than 25Pa in 6 minutes. The pressure hold test is carried out at the operating pressure of 250Pa.

7.2.4 The leak test is carried out semi automatically, the operator places leak test bungs into the air inlets and the air extracts to each isolator chamber, the alarm system then automatically carries out the test with the following sequence:

7.2.5 The isolator generates the required leak test pressure with an overpressure of 75Pa to ensure that the leak test is carried out above the normal operating pressure.

7.2.6 Before the leak test proper starts the control, unit allows a stabilisation period to allow the glove/sleeve to accept the new pressure conditions.

7.2.7 The control system then carries out the leak test and displays the start pressure, the elapsed time and the current pressure.

7.2.8 On completion of the test the display shows if the isolator has passed or failed the test and displays the start pressure, the end pressure and the pressure drop.

7.2.9 The starting pressure and end pressure are displayed on the alarm unit accepted by the operator when the control system logs the leak test result together with the date and time of the test.

7.2.10 The test results are then printed out via the onboard thermal printer. The report prints the information as detailed above. The report also has a signature box for the operator to sign the test off in.

7.3 Leak Testing – Optional Extra (Fully-automated)

7.3.1 As an optional extra the Isolator leak Classification test can be demonstrated by means of a fully automated pressure hold test, which is simple to carry out. This test carries the leak test on the Process Chamber of the isolator.

7.3.2 The complete isolator can also be tested using the same procedure however the operator is required to unseal and remove the inner door then fit leak test bungs into the air inlet and extract positions within the transfer chamber.

7.3.3 Negative Pressure isolators are classified as Class 2 (ISO 14644-7) which is equivalent to an hourly leak rate of 2.5×10^{-3}.

7.3.4 The standard decay test for a Class 2 isolator is a pressure change of less than 25Pa in 6 minutes. The pressure hold test is carried out at the operating pressure of 250Pa.

7.3.5 The Process Chamber leak test is carried out fully automatically, the operator selects “leak test” from the control system menu, the control system then automatically carries out the test with the following sequence:

7.3.6 The isolator generates the required leak test pressure with an overpressure of 75Pa to ensure that the leak test is carried out above the normal operating pressure.

7.3.7 Before the leak test proper starts the control, unit allows a stabilisation period to allow the glove/sleeve to accept the new pressure conditions.

7.3.8 The control system then carries out the leak test and displays the start pressure, the elapsed time and the current pressure.

7.3.9 On completion of the test the display shows if the isolator has passed or failed the test and displays the start pressure, the end pressure and the pressure drop.

7.3.10 The starting pressure and end pressure are displayed on the alarm unit accepted by the operator when the control system logs the leak test result together with the date and time of the test.

7.3.11 The test results are then printed out via the onboard thermal printer. The report prints the information as detailed above. The report also has a signature box for the operator to sign the test off in.

7.4 Leak Testing – ‘Out of Hours’ (Part of Optional Extra Fully Automated Testing)

7.4.1 One of the features of the fully automated leak test is that the unit can be set up to carry out a leak test ‘Out of Hours’.

7.4.2 This function can be simply switched On or Off via the control system and the time at which the test takes place can be altered to suit the customer’s needs.

7.4.3 The leak test is carried out as detailed above and a report printed in the same way so that the operator can easily see the isolator is suitable to use.

7.5 Door Seal Integrity Test

7.5.1 The isolator can also check the integrity of the door seals by carrying out a vacuum hold test on the door seals. The test is carried out automatically and runs for a maximum of 3 minutes.

8 Standards

8.1 Isolator and Cleanroom Standards

BS EN ISO14644	Cleanliness Clean rooms and Controlled Environments
Part 1: 1999	Classification for Air Cleanliness
Part 2: 2000	Specifications for testing and monitoring to prove continued compliance with Part 1
Part 3: 2005	Test Methods
Part 7: 2007	Separative Devices
ISO 10648: 1994	Containment Enclosures
ISBN 011 701829 5	Isolators for Pharmaceutical Applications

8.2 Safety Standards

Machinery Directive	89/392/EEC
Electromagnetic Compatibility Directive	89/336/EEC
Low Voltage Directive	73/23/EEC

8.3 Electrical Test Standards

Code of Practice for acceptance testing of Electrical Mechanical Equipment	HEI No 95
Code of Practice for acceptance testing of Electronically operated Hospital Laboratory Equipment	HEI No 140
Electrical Safety Code for Hospital Laboratory Equipment (ESCHLE)	HEI No 09
Safety Requirements for electrical equipment for measurement control and laboratory use	CEJIEC 1010-1 Part 1
Electrostatic discharge tests	IEC 801-2
Radiated and Mains emission	BSEN 55022 Class A & B
Electrical Test Certificate	Minor Electrical Installation Works
(tested at Amercare's premises prior to delivery / installation)	(BS 7671 – IET Wiring Regulations)

9 Installation, Service and Extract Requirements

9.1 General Installation

9.1.1 The isolator is designed to pass through a standard single door for ease of installation.

9.1.2 Minimum access of 250mm is required to either side of the isolator after installation to allow for airflow to inlets and general cleaning.

9.1.3 Minimum of 500mm of clear space is required above the isolator when it is in the fully up position. See the General Arrangement drawings in Section 13 of this document for detail dimensions.

9.2 Electrical Power

9.2.1 A single electrical supply of 240 VAC-13A is required for the Isolator System. This can be either a Fused Spur or an Electrical Socket

9.2.2 The isolator is equipped with a single Residual Current Device (RCD) and Miniature Circuit Breakers (MCBs) for each of the main circuits, Control system, lights and sockets, fans.

9.2.3 Operating current < 3 amps

9.2.4 Start-up current < 5 amps

9.2.5 Heat gain to room < 600W

9.3 General Services

9.3.1 The isolator requires no services other than the electrical connection.

9.4 Airflow and Extract Requirements for ducted Isolators

9.4.1 For ducted isolators a flexible PVC duct is provided by Amercare for the discharge air from the isolator. The flexible duct should have sufficient free length to allow height adjustment of the isolator, and for the isolator to me moved for cleaning and maintenance.

9.4.2 The volumetric flow rate and pressure requirements are shown in the Information Section (Section 12) of this document.

9.4.3 An extract fan of suitable duty to provide the airflow required for the isolator, plus any ductwork pressure losses should be provided. The fan would normally be located in a local plant room, or externally, but in any case close to the discharge point. This will ensure that ductwork between the isolator and the extract fan will be under negative pressure.

9.4.4 A suitable connection for the isolator flexible connection should be provided within the room. The connection should be 160mm external diameter and have a minimum length of 150mm below the ceiling to connect the flexible ducting onto.

9.4.5 Amercare can supply extract fans which are suitable for remote mounting and which will generate the correct air flow conditions for the isolator during both normal running and isolator testing. Where a fan is supplied by a third party the fan performance must be checked with Amercare prior to installation of the isolator.

9.5 Exclusions

9.5.1 Extract System

The specification is exclusive of extract system ductwork and extract fan.

The supply of the extract fan can be quoted for separately. Extract systems with either long or convoluted duct runs may require a different extract fan to the one quoted for as standard.

9.5.2 Building Works

The specification is exclusive of any building works and/or making good thereof.

9.5.3 Electrical

The Electrical supply (socket or Fused Spur) should be adjacent to Isolator to minimise tripping hazards.

10 Supplied Accessories & Spares

10.1 Accessories

10.1.1 Leak Test Bungs

The isolator is supplied with a full set of Leak Test Bungs required to carry out the regular leak testing of the isolator

10.1.2 Electrical Socket Plug

The isolator is supplier with the mating plug for the electrical socket fitted, as standard, to the isolator. When correctly assembled this socket / plug assembly creates an IP68 rated leak tight joint.

10.1.3 Baffle Adjustment Key

The adjustment key required to adjust the onboard baffles to alter pressures / airflows within the isolator's chambers is supplied with all new isolators.

10.2 Spares

10.2.1 Gauntlets & Sleeves

The isolator is supplied with spare gauntlet or sleeve of the same material to those fitted will be provided in addition to those fitted on the Isolator.

10.2.2 Vacuum Door

The isolator is supplied one spare Vacuum Door Assembly.

11 RadioPharmacy Isolator Options

11.1 Centrifuge (Blood Cell Labelling isolators only)

The Blood Cell Labelling isolator features a fully integrated centrifuge as part of the main chamber.

The well of the centrifuge is fully welded to the main chamber carcase. The motor for the centrifuge is mounted externally to this to ensure that generation of particles are kept to a minimum and that if is safe to fully clean the well using IMS / IPA without fear of issues with these products coming into contact with electrical components.

The centrifuge come fitted as standard with a two-bucket rotor. A four-bucket rotor is a cost option. The buckets are designed to fit vials of up to 50ml. A range of inserts are available to fit the generally used vials.

The centrifuge has a maximum spin speed of 3300 rpm (1948 RCF), this is controlled via the isolator's standard control system.

The centrifuge has a lid that features a vacuum sealing system as per the isolator's doors. There is also a mechanical lock for added safety. This lock needs to be in the closed position before the centrifuge can operate.

11.2 Automated Leak Testing

As a cost option the isolator can be fitted with automated valves that enables the isolator to carry out unmanned leak tests of the Process Chamber.

The fully automated leak test removes the need for fitting bungs and closing valves to perform the isolator leak test. This removes any operator errors from this part of the leak test.

Automating the test also allows the unit to perform leak tests out of hours. This means the leak test can be carried out either overnight or early in the morning before staff arrive and the room pressures are affected by the doors being opened and closed.

The automated leak test also means that the department's staff can start work straight away knowing that the isolator is in a classified condition.

The results of the automated leak test are printed via the fitted on-board thermal printer. The automated valves have designed into them a bypass feature so that the air that normally passes through the isolator directly enters the extract ductwork.

11.3 Bluetooth Thermal Report Printer

To avoid the presence of paper in the clean room the Report printer option is available as a portable printer connected by Bluetooth to the isolator.

All of the features for the Bluetooth printer are as per the standard Report Printer detailed in Section 3 of this specification

11.4 Lead Acrylic (Premac®) Glove Port Panels

RadioPharmacy isolators are available with the option of fitting Premac® (Lead Acrylic) Glove Port panels in place of the stand acrylic items

The Premac panels are available in four different thicknesses each of which offer differing levels of radiation protection

Premac® lead acrylic is a lead loaded acrylic copolymer resin with particular shielding properties.

The material is transparent with a very light brown tint, exhibiting virtually all the normal chemical and physical properties of conventional acrylic

The Lead Acrylic panels are available in the following four thicknesses

Premac Thickness	Approx. Lead Equivalent [1]
18mm	0.9mm
22mm	1.1mm
35mm	1.7mm
46mm	2.2mm

[1]100 to 200kV narrow beam transmission as verified by the Health Protection Agency, Harwell, UK

11.5 Dose Calibrator

All Amercare Radiopharmacy isolators have the option to be fitted with a Dose Calibrator

As standard a Capintec CRC55tR dose calibrator would be supplied. However other makes and models can be integrated into the isolator if required.

This is fully integrated into the floor of the Process Section of the isolator

The calibrator can have the samples to be measured manually placed into the chamber using an Acrylic Dipper or using the optional Autodipper system.

Key features of the Capintec CRC55tR are:-

- 8" colour VGA touch screen display
- Chamber plug-and-play capability
- Selection of Nuclide and Daily Test
- On screen display of Nuclide Name, Number, Activity, Unit of Measure and Calibration Number
- Large character, high visibility display
- Over 80 Nuclides with half-lives in memory
- Full alpha numeric touchpad
- Built-in dose calibration, quality control and self-diagnostics

11.6 Calibrator Autodipper

All Radiopharmacy isolators have the option to be fitted with a Calibrator Autodipper

When fitted the Autodipper assembly moves a bobbin that carriers either a vial or syringe containing the sample that that requires its activity measuring via the Ionization Chamber.

Automating this process with help reduce hand dose to the operator(s).

The movement of the bobbin is controlled by a foot operated switch meaning that there is no need to remove your hands for the gloves to operate the Autodipper.

The system is designed so that through the use of different inserts a wide range of either vials or syringes can be safely located in the bobbin.

11.7 Continuous Particle Monitoring

As a cost option the isolator can be fitted with the parts required to allow the connection of the isolator's main chamber to an external particle counter to continuously monitor, in use particle levels.

The system consists of an isokinetic sampling head, a flexible support to allow for the sampling head to be positioned near to the point of fill, and a shut off valve to enable leak testing of the isolator.

The assembly is also supplied with a cover cap to place over the isokinetic sampling head to protect the counter when cleaning products are being used within the isolator.

Not fitting the cap when using cleaning products can cause spikes of particles being recorded or damage to the internals of the particle counter itself.

The particle counting body is mounted externally to the isolator with a manual valve to isolate the counter from the process chamber when leak testing.

The CPM system is compatible with many different manufacturers 1cfm particle counting systems.

11.8 Glove Leak Tester

11.8.1 Negative Pressure Isolators

Negative Pressure Glove Leak Testers are available as a cost option. These have been designed so that operators can quickly and easily check that there are no leaks in the fitted gauntlets / sleeve-gloves.

This enables the operator to ensure that the isolator's process chamber integrity is not being compromised by leaks in the fitted gauntlets / sleeves.

11.8.2 Automated Glove / Cuff Tester

The Automated Glove Leak Tester is available for isolators fitted with Sleeves and the Amercare Easy Change Cuff System.

The tester takes advantage of the air pumps and pressure transducers which are already part of the Isolator to provide a really quick and fully automatic leak test on the gloves.

Each glove can be quickly checked at the start of each session and the printout provides a record that the test has been carried out correctly. (The panel printer is an option which also provides comprehensive reports for isolator as well).

Each glove takes about a minute to test so even a 4-glove isolator can be fully tested in less than 10 minutes.

The onboard thermal printer prints a test report following each test (Glove).

11.9 CCTV Camera

CCTV cameras can be used for training, quality control and auditing purposes within isolators.

11.9.1 Bullet Style Camera

All RadioPharmacy isolators have provision for mounting a CCTV camera into the rear wall of the Process Chamber.

Cameras can be fitted at the time of manufacture but can also be fitted at any time after installation with a minimum of disruption.

Options for viewing and storing images include both conventional TV monitors/video and PC based viewing and data storage.

Remote viewing possible through network or internet connection.

Note: It is not possible to specify an isolator with both Continuous Particle Monitoring AND a Bullet Style CCTV Camera as these features use the same mounting hole in the carcase.

Whilst this option is still available on our isolators it is now viewed as an old technology.

We recommend using the PTZ Camera option detailed below is the integration of a CCTV Camera is required

11.9.2 PTZ Camera

A PoE (Power Over Ethernet) PTZ (Pan, Tilt, Zoom) CCTV camera to be mounted external to the primary working chamber that then, through a clear cast acrylic window (bonded to the carcase to ensure leak tightness) provides an overview of operations within the chamber.

The CCTV Camera will be specified with suitable zoom capabilities to enable product checking with sufficient clarity to ensure the details of the product can be clearly read.

Specifications of the camera to be agreed with both the users and those responsible for providing cabling and viewing infrastructure.

11.10 Extract Bypass Valve

All Amercare isolators can be supplied fitted with an optional Bypass Valve. This item can also be retrospectively added at a later date if required.

The valve is designed so that when isolator leak tests are carried out the air that normally passes through the isolator and into the extract duct during normal operation passes straight into the extract duct.

This means that the room pressures are not affected during the leak test due to the change in air extract volume.

Changes in room pressures can have a major effect on leak test results.

All isolators supplied with the option of the fully Automated Leak Test do not require this option as a Bypass system is designed into the Automated valve assembly.

11.11 Connection to BMS / EMS / Monitoring Systems

All Amercare isolators can be supplied with the option of a Volts Free signal that can be connected up to BMS / EMS systems (supplied by others).

The isolator can give a signal for the two latched alarm conditions. These are

- Mains Power Failure
- Probable Extract Fan Failure

Additional Pressure Transducers (supplied by others) can also be fitted to the isolator to provide information to external monitoring systems of the pressures within any isolator section.

Please note that as standard Amercare are unable to provide any electrical supply required for these transducers.

Note: When fitting a second source of pressure measurement Amercare recommend the customer invests in a hand-held manometer. This can then be used as a reference to identify which of the two systems is displaying an incorrect reading due to drift in the calibration of that particular transducer.

12 Information

12.1 Dimensional Information

		Overall Dimensions		
Product Code	**Description**	**Length**	**Depth**	**Max. Height (Range)**
A2/CIN23B?	3 Glove Process	1665mm	740mm	1540mm ~ 1840mm
A2/CIN24B?	4 Glove Process	2065mm	740mm	1540mm ~ 1840mm
A2/N/3/B-*ME	3 Glove Process, Manipulating Transfer Chamber	2480mm**	740mm	1540mm ~ 1840mm
A2/N/4/B-*ME	4 Glove Process, Manipulating Transfer Chamber	2880mm**	740mm	1540mm ~ 1840mm

? – The single transfer chamber is fitted, as standard to the Right-hand side of the Process Section. It can however be fitted to the Left-hand side. To order this option add REV to the end of the product code

* - Can be either L (Left-hand) or R (Right-hand)

** - End access is required. This needs to be about 500mm

Isolators that recirculate the extract air back into the cleanroom are 150mm taller than the standard extracted isolators.

12.2 Air Change Rates

Chamber Type / Size	Low Flow Standard Alarm Set Point	Operating Range – Changes per Hour	
Standard Transfer Chamber	120	500	1600
Manipulating Transfer / Elution Chamber	120	120	400
1000 Process Chamber (2 Glove)	120	120	360
1200 Process Chamber (3 Glove)	120	120	285
1600 Process Chamber (4 Glove)	120	120	210

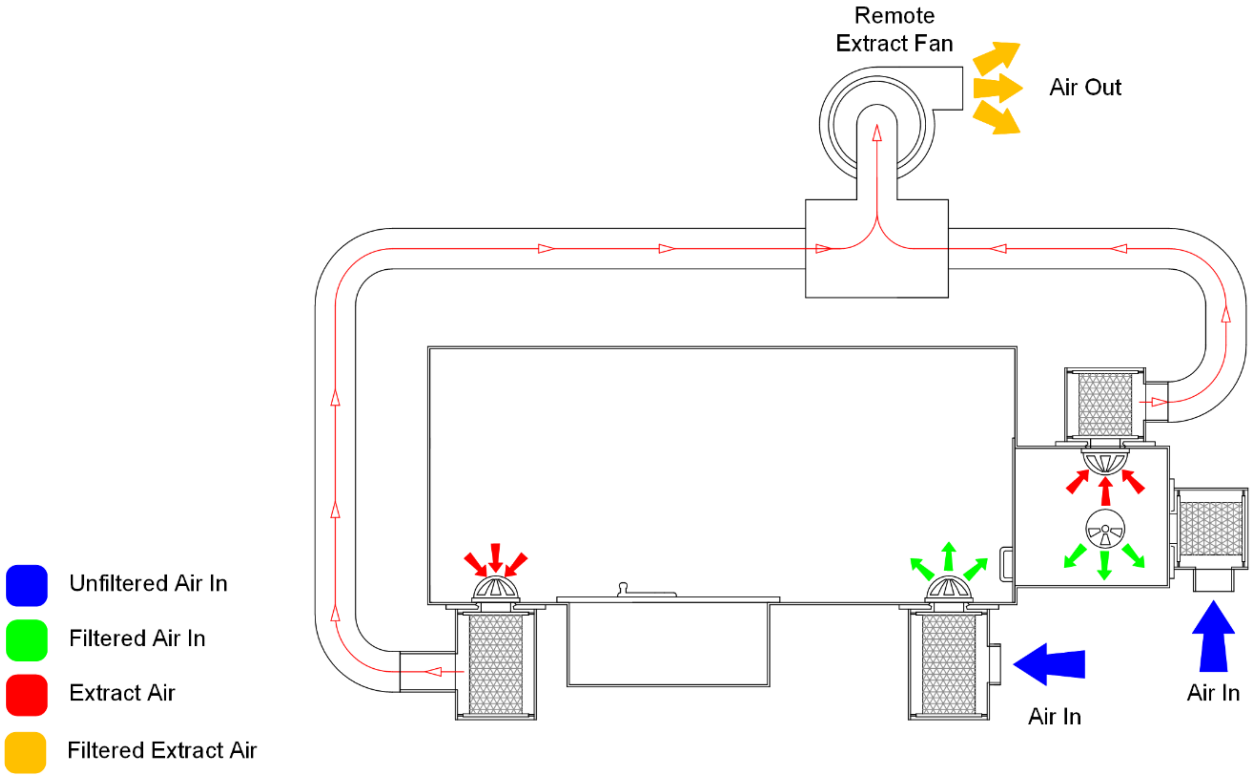
12.3 Isolator Sections with Air Flow Monitoring

Isolator Type	Process Chamber	Transfer Chamber(s)	Manipulating Transfer Chamber
Negative Pressure Pharmacy	**X**	**O**	**X**
Positive Pressure Pharmacy	**X**	**X**	**X**
RadioPharmacy	**X**	**X**	**X**

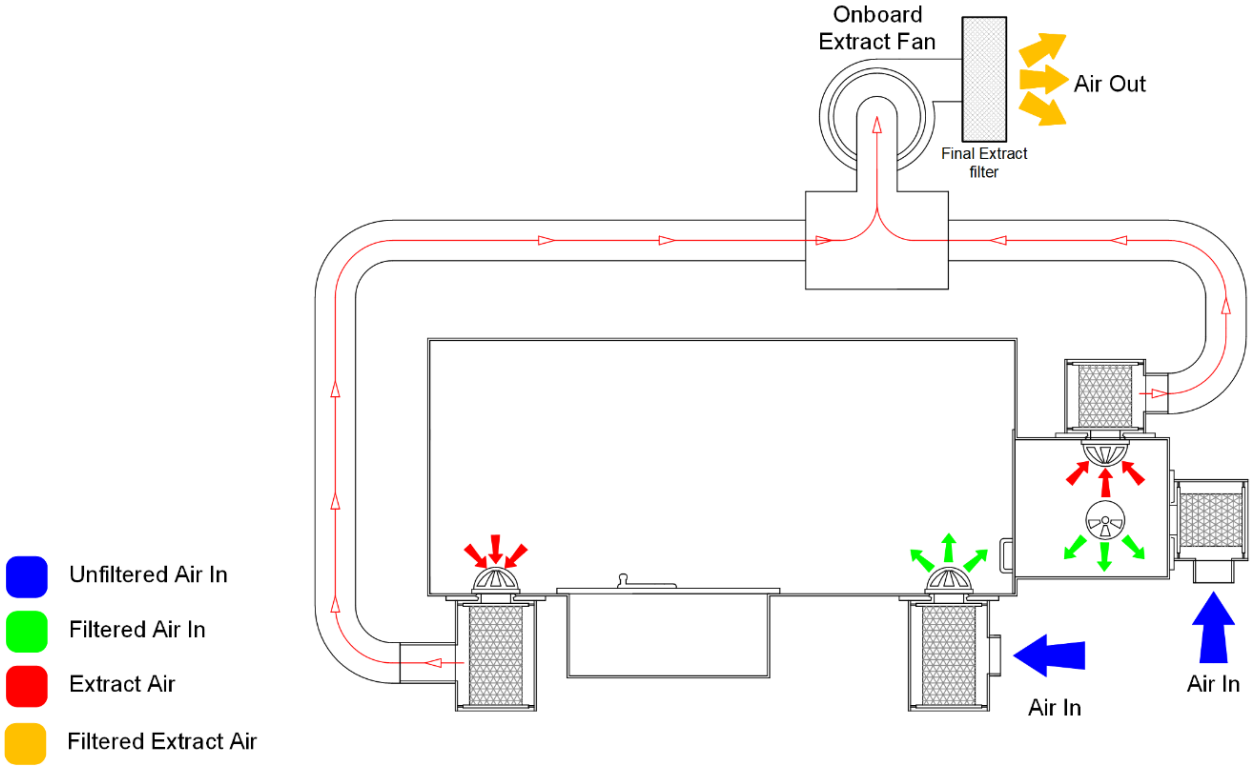
X - Standard
O – Cost Option

12.4 Airflow Diagram

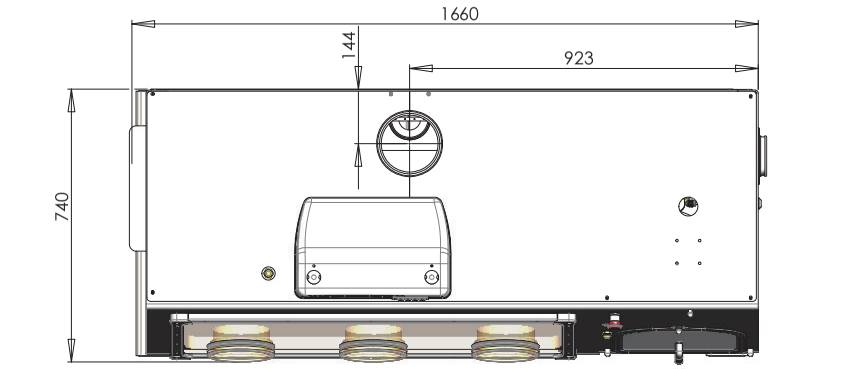
12.4.1 Blood Cell Labelling (Ducted)

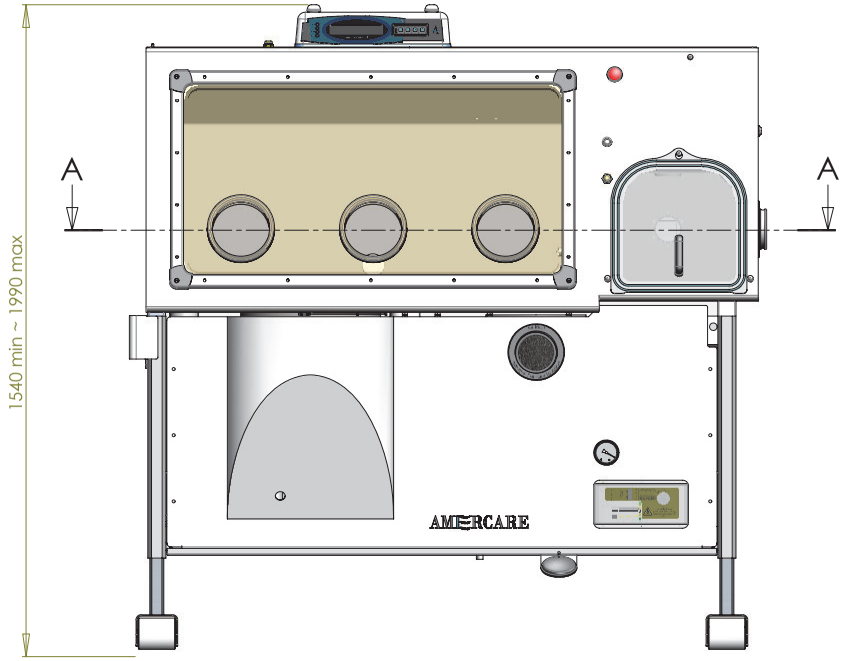


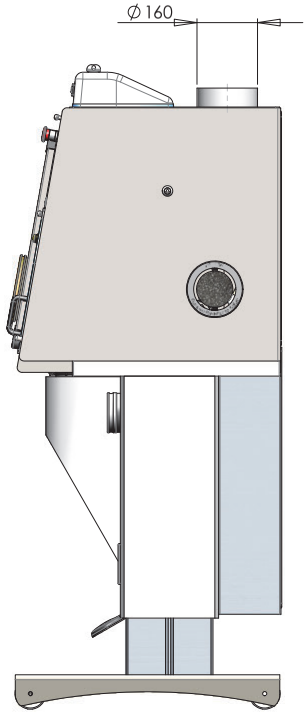
12.4.2 Blood Cell Labelling (Recirculating)

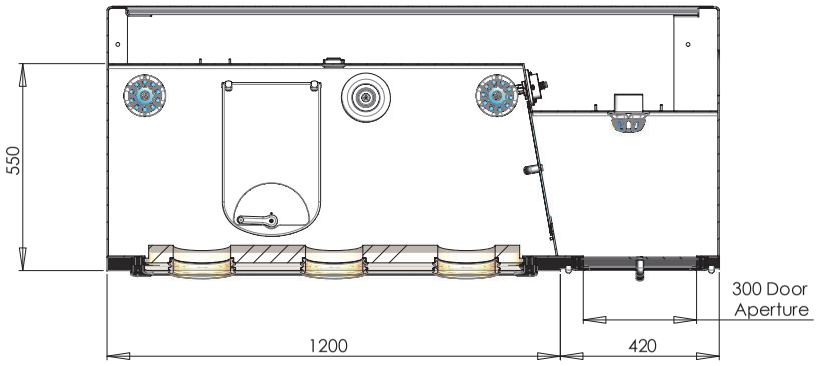


13 General Arrangement Drawing









Third Angle Projection - Drawing conforms to BS308

Installation Details

Electrical Services

An electrical supply of 240 VAC - 13A is required for the isolator
Actual current draw is approximately 3A @ 240 VAC

(Please note 110 V version available)

Ventilation System

The ventilation system should meet the following specifications

Extract Fan

The fan should be able to produce a flow of 212 m3 / hr (125 cfm),
and a static pressure of 650 Pa

Fan Electrical Supply

The fan can be supplied with either a single or three phase motor.
The motor size is 0.75 kW (750W), the Full Load Running Current
is 5.1A at 240 VAC.
If a single phase supply is used then the motor draw a current of 14A at start up.
Circuit breakers must be sized to accomodate this start-up current.

Ducting

The ducting can be either plastic (PVC-U) or galvanised mild steel.
The diameter of the ducting needs to be a minimum of 160mm.

Air Quality

During normal operating the air quality within the isolator meets
Class 100 / European Grade A standards.
Each module of the isolator is provided with it own 99.997& HEPA filter for both inlet and extract filters

Weight

Total weight of isolator = 300 kg

	Mod No.	Drawn	Date	Checked	Mod Box
		MJB	12/12/07		

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AMERCARE

Title A2/CIN23B Installation Details

Used on	Job	Job No.	Scale	DRG. NO.	Issue	SHT 1 of SHT 1
	A2 Blood	A2B	1:10	2AB9622	A	