

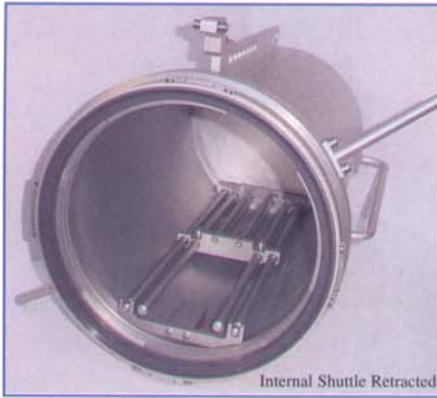


Dynamic Design Pharma

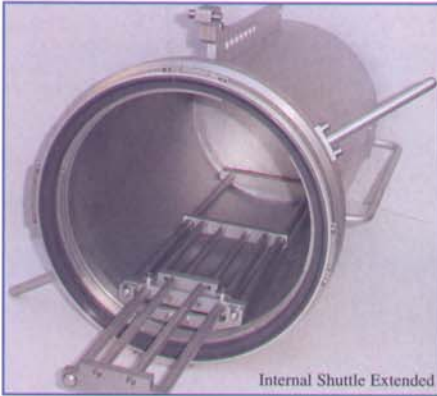
NRC System

Beta Flange with Non-Rotating RTP Canister





Internal Shuttle Retracted



Internal Shuttle Extended



Internal Parts Tray Retracted



Internal Parts Tray Extended

SYSTEM DESCRIPTION

- ✧ The Non-Rotating canister (NRC) is a RTP canister system featuring an innovative beta flange that, by means of a custom bearing system and dynamic seal, is free to rotate in relation to the canister. The NRC beta flange is designed to interface with industry standard RTP ports.
- ✧ The NRC canister, in its standard form, is a cylindrical canister with an internal shuttle mechanism designed to hold a parts tray. It also features lifting handles and self-supporting devices that permit hands free docking of the NRC onto the RTP port.
- ✧ The patented NRC's beta flange yields the benefit of total versatility in the design of the canister body. It can be manufactured in many different shapes, sizes and materials, as required by the application at hand.

ADVANTAGES

- ✧ The non-rotating characteristic of the NRC canister permits applications that are impossible to implement with today's RTP canister technology.
- ✧ The shuttle and tray hardware permit the safe transfer of heavy or delicate parts into and out of isolator systems.
- ✧ The canister body does not rotate. As a result, it has handling features and self-supporting devices that make its transport and docking safe for the operator.

APPLICATIONS

- ✧ Sterile machine parts transfer into the isolator system during the Change Over process between production lots.
- ✧ Sterile machine parts introduction and removal during campaign style production.
- ✧ Production supplies introduction such as micro supplies, environmental monitoring supplies, sanitization supplies.
- ✧ Continuous material flow such as stoppers introduction, powder loading or rejects removal.

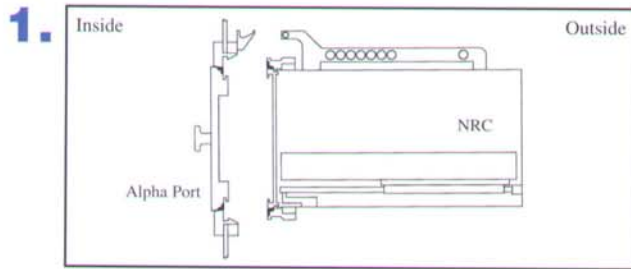
FEATURES

- ✧ Aluminum or stainless steel beta flange and canister body.
- ✧ Custom bearing system and dynamic seal that permit rotation of the beta flange relative to the canister body.
- ✧ Standard or custom designed canister body, as required by the application.
- ✧ Self support devices that permit docking the NRC to the RTP port without having to support the weight of the canister during the process.
- ✧ Interface features to the Lift/Transport manufactured by Dynamic Design Pharma. This yields a totally safe method of handling the potentially heavy canisters inside the manufacturing facility.
- ✧ Internal shuttle mechanism that serves the function of safely attaching a tray to the NRC canister body. Ideal for safe handling of heavy machine parts into and out of isolator systems. The shuttle permits pulling the tray out of the NRC for easy reach of the components housed internally.
- ✧ Internal tray, in its standard form or custom designed to the application that attaches to the shuttle without tools and permits safe handling of components.

SPECIFICATION

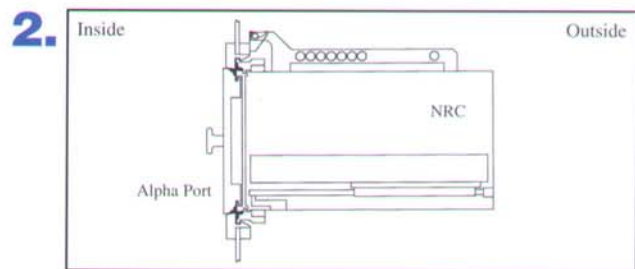
- ✧ Nominal beta flange size: 350mm, 270 mm, 190mm.
- ✧ Weight of 350 mm size (aluminum) with shuttle and tray: 22 kg.
- ✧ Part handling capability: 40 kg.
- ✧ Length of standard canister body: 550mm.
- ✧ Material: 6061-T6 aluminum alloy or 304 stainless steel.
- ✧ Leak tightness: Capable of passing ammonia leak test when pressurized to 50 pascal internal pressure.
- ✧ Interface with industry standard RTP ports.
- ✧ Capable of withstanding the temperature of steam sterilization and the surface effects of Vapor Hydrogen Peroxide gas decontamination.

DOCKING SEQUENCE



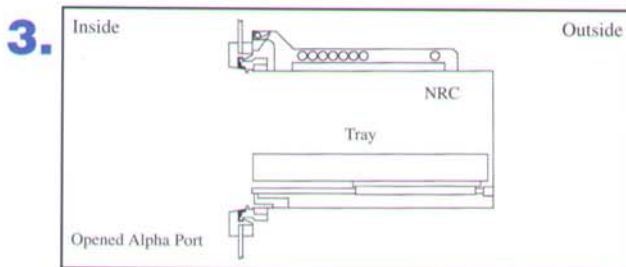
NRC ready to dock RTP port

1. The NRC is moved into proximity to the alpha flange of the RTP port.
2. The support hook engages the mating cradle on the RTP port to avoid having to support the canister's weight during docking.
3. Alternatively, if the NRC is connected to the Lift Transport system, its weight is supported at all times during the docking process.



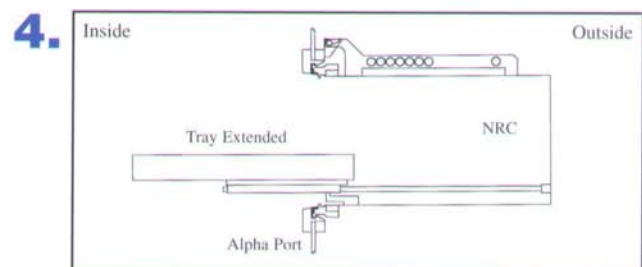
NRC is docked onto the RTP port

1. Once the alpha and beta flanges are placed into contact with each other, the beta flange is rotated to complete the docking process.
2. The canister body does not rotate, permitting the internal components to remain stationary.
3. The support hook remains engaged at all times, ready to support the system weight upon undocking.



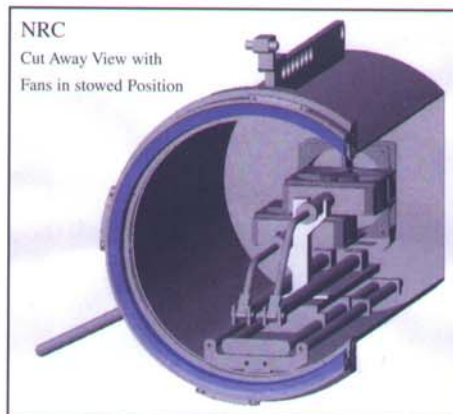
Alpha/beta door is opened

1. Once the docking process is completed, the alpha/beta door is opened from inside the isolator.
2. The operator has access to the internal volume of the NRC.



Access to components inside

1. The components tray is pulled out of the NRC body. It is supported at all times by the NRC's internal shuttle.
2. The operator uses the isolator gloves to access the parts held inside the tray.



AIR MIXING MODULE

For VHP Decontamination of Barrier Isolator Systems

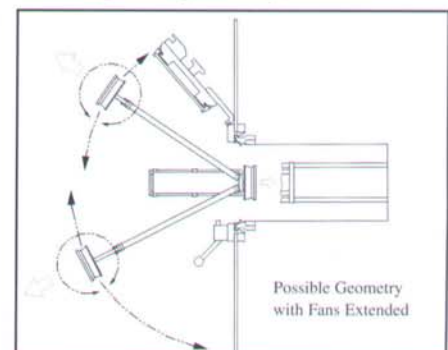
A system that docks onto a standard port of the barrier isolator for the purpose of creating air turbulence within the isolator chamber during Vapor Hydrogen Peroxide (VHP) decontamination. It consists of a Non-Rotating Canister (NRC) containing three fans that are extended out of the canister body and into the isolator chamber before starting the VHP cycle. The three fans are attached to a manually activated shuttle that is housed inside the NRC. This method of attachment results in repeatable positioning and orientation between VHP cycles. Two fans are mounted on individual swing arms that reach well into the isolator system. A third fan, hard mounted to the shuttle mechanisms, creates air turbulence and within the NRC thus assuring good VHP coverage of internal surfaces. At the end of the VHP cycle, the fans are stowed back into the NRC by the operator through the isolator gloves. The design of the system's such that the stowing operation can be accomplished by touching surfaces that have been decontamination by the VHP cycle.

ADVANTAGES

- ✦ Eliminates the need of permanently mounted air mixing fans inside the isolator systems.
- ✦ Uses Non-Rotating canister technology: hands free handling of heavy components to be transferred into and out of isolators.
- ✦ Directional control of airflow during smoke studies and VHP cycle development.

SPECIFICATION

- ✦ Normal RTP port size: 270mm and 350mm..
- ✦ Total number of fans: 3 (2 adjustable, 1 fixed)
- ✦ Electrical requirements: 115Vac 60hz or 220Vac 50hz



NRC OPTIONS and ACCESSORIES

- ❖ **HIGH PRESSURE SYSTEM** - Intended for those applications that require 40 psi pressurization of the NRC during autoclave sterilization. The option consists of a pressure closure cap that applies a compression seal to the NRC's beta seal and to the internal dynamic seal.
- ❖ **SUPPORTING CRADLE** - Designed to hold the NRC during component loading while inside the autoclave. The cradle securely holds the NRC in the horizontal orientation and features a series of rollers that permit free movement of the NRC on the autoclave cart.
- ❖ **BETA DOOR INSTALLATION/REMOVAL TOOL** - This tool engages the external lugs of the beta door and permits easy installation and removal of the beta door onto the beta flange.
- ❖ **ABSOLUTE FILTER PORT** - Connection, as required by the application, available in 1 inch, 1-1/2 inch or 2 inch standard triclover flange.

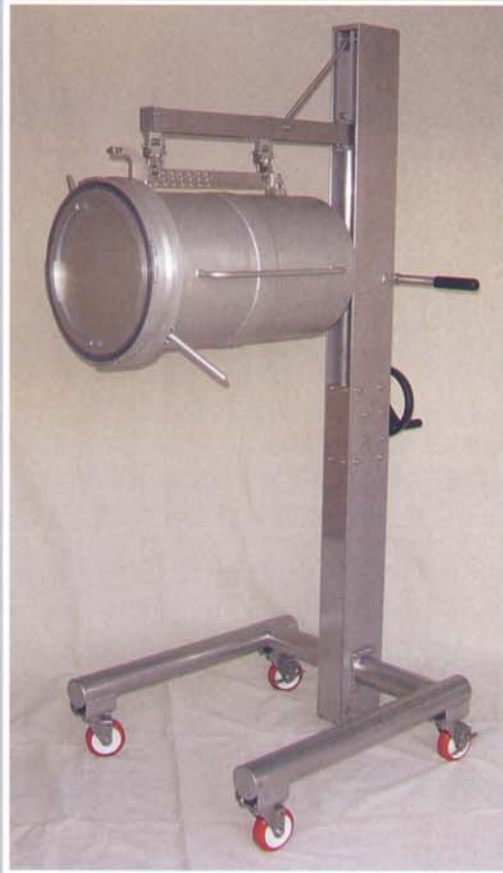
Lift/Transport System

SYSTEM DESCRIPTION

The Lift/Transport System is a clean room device that is designed to interface with the Non-Rotating Canister (NRC). The Lift/Transport System provides means of docking, undocking and transporting the NRC canister without requiring the operator to support the weight of the canister. A safe, hands free docking process. The Lift/Transport System supports the NRC canister by suspending it from appropriate hooks. It features a manual drive mechanism which permits the operator to bring the NRC into vertical alignment with the RTP port alpha flange or other transporting devices as required by the operation. The angle of the NRC supporting beam can also be adjusted to bring the suspended NRC canister into proper angular alignment with the RTP port. The Lift/Transport System features polyurethane non-marking and lockable casters that permit easy and safe movement of the system throughout the manufacturing facility.

FEATURES

- ❖ Stainless steel welded base with four casters.
- ❖ Vertical drive system to raise and lower the canister support assembly by turning an external hand wheel.
- ❖ Fixed handle for system movement by the operator within the facility.
- ❖ Supporting beam whose angular alignment to the horizontal plane can be adjusted as required by the application.
- ❖ Support assembly that suspends the NRC canister into alignment with the RTP port.
- ❖ NRC interface hooks that are fixed in the for/aft direction but are free to swing in the side to side direction to facilitate the hook up process of the NRC canister to the alpha flange.
- ❖ The interface hooks have safety gates that swing down to lock onto the NRC canister.
- ❖ Adaptable to interface with standard RTP canisters.



SPECIFICATION

- ❖ Weight without NRC canister 50Kg (110 lbs)
- ❖ System height: 1869 mm (73.7 inch)
- ❖ Vertical travel: 591 mm (23.7 inch)
- ❖ Drive resolution: 2.54 mm/turn (0.1 inch/turn)
- ❖ Horizontal tilt requirement: +/- 10 degrees from horizontal
- ❖ Caster: Polyurethane rubber, no marking, swivel type
- ❖ Lubrication: None required in any of the drive components
- ❖ Material: Stainless steel external components



DYNAMIC DESIGN PHARMA INC. ~ 24241 Tama Lane Laguna Niguel, CA 92677 ~ Phone (949) 643-1120 ~ Fax (949) 643-1012

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