

Introduction

Saunders HC4 Bio-Block Design & Specification Programme forms part of the extensive range of innovative products and services available to the Biopharmaceutical customer. Our range is complemented perfectly by Saunders full range of standard Two Way BPE Compliant Forgings, Machined Zero Deadleg configurations and Custom fabrications. All body configurations are available with full material traceability and are available with Saunders unique range of Diaphragms - every permutation being FDA conforming, USP Class VI tested and fully traceable to raw ingredients. Furthermore, all products within our portfolio are available with a modular range of both Stainless Steel and high performance polymer manual and actuated bonnet options and a full range of accessories.

Whether product, technical or service related, Crane Process Flow Technologies have evolved a unique set of criteria to meet the increasingly complex challenges faced by the Biopharmaceutical Industry.

Contact your local Saunders Diaphragm Valve channel, call us or alternatively visit our website www.saundersvalves.com or www.craneflow.com

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SECTION 1

Saunders HC4 Bio-Block Design

- 1.1 Bio-Block Philosophy
- 1.2 Bio-Block Design Principles
- 1.3 Bio-Block Design Criteria
- 1.4 Glossary of terms
- 1.5 Virtual Reality Modelling Language (VRML) tool
- 1.6 Bio-Block Overview

1.1 Saunders Bio-Block Philosophy

We create custom solutions to meet the unique demands of the bio-pharmaceutical processing industries through the use of advanced 3D computer design software, direct tool interface and advanced manufacturing technology.

Crane Process Flow Technologies Ltd. (CPFT) and our staff of highly trained specialists are dedicated to supporting our customers with the most effective solutions to the most critical and demanding applications in the market.

By working with our customers from the early stages of a project through the installation process, we are able to support our customers in the selection and specification of the optimum Bio-Block option.

1.2 Bio-Block Design Principles

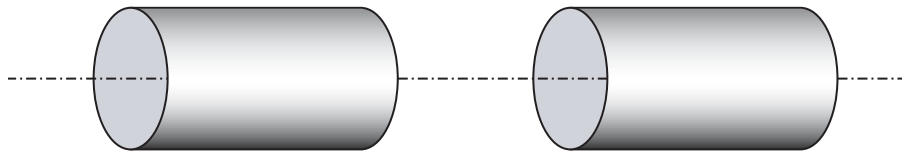
- Designed and engineered using 3D CAD engineering software
- Manufactured from solid block using 3D direct tool interface software on multi-axis machine centers
- First key design concept is a combination of bore chamber/weir and fitting - as in zero deadleg tee
- Second key design concept is common or shared chamber/weir as in multi-port valve
- Complex solutions can be achieved using combinations of shared chamber/weir and/or chamber/weir and fitting
- Weirs will drain with piping in vertical installation
- Weirs must be inclined to drain in horizontal installation
- Drain points of all wetted components including weirs, valve bores and tubing, must be considered for completed assembly to drain
- Allowance must be made for body fasteners and for diaphragm maintenance

- Manufacture from solid block to eliminate internal fabrication welds
- Produce assembly with highest levels of structural integrity
- Reduce deadlegs, stagnant areas and total wetted area
- Resultant design must fully drain
- Reduce total design envelope
- Eliminate or reduce dead legs and stagnant areas
- Minimise total wetted areas
- Reduce number of components and associated pipework
- Facilitate field fit up and installation
- Design must use standard range diaphragms, bonnets and actuators without requiring special adaptors

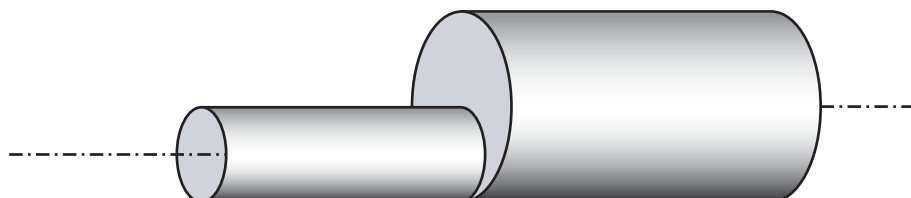
1.3 Bio-Block Design Criteria

To enable valves and tubing to fully drain in a horizontal orientation:

Valve and tube centers must coincide when line sizes are equal



Valve and tube centers must differ when line sizes are not equal



Drain points of tubing, valve bores and valve weirs must coincide to fully drain a valve assembly.

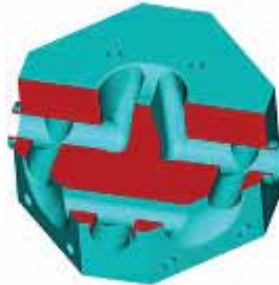
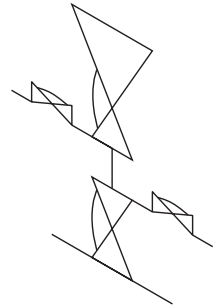
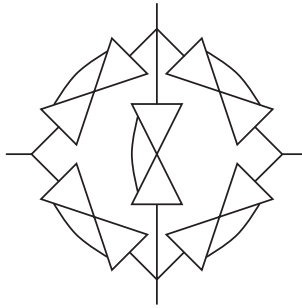
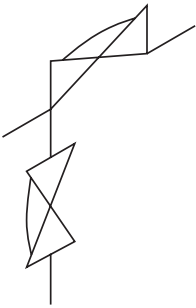
Vertical weirs always drain



Horizontal weirs must be inclined at a self drain angle to permit fluid to drain

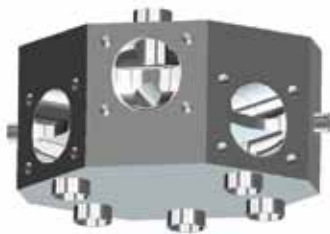
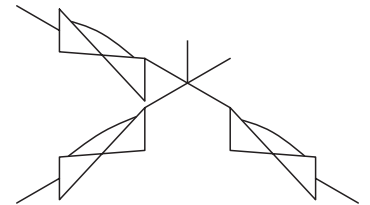
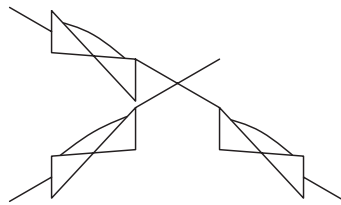
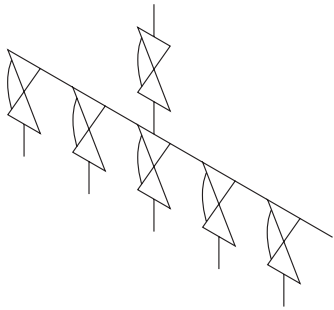


Flow paths must conform to valve function



Design should strive to reduce deadlegs and total wetted area

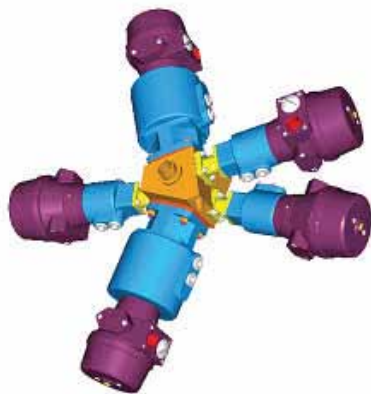
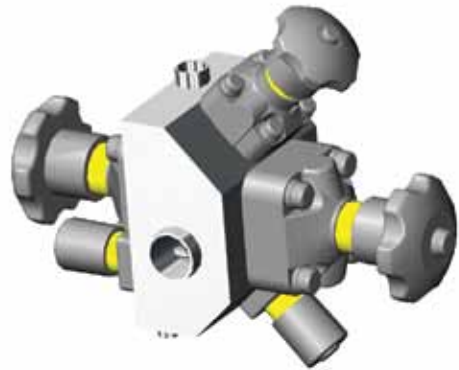
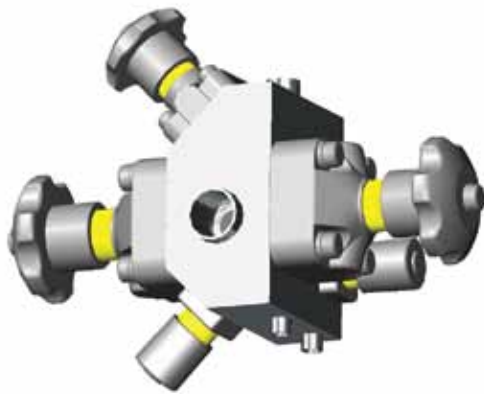
Design must consider vertical, horizontal and mixed piping arrangements



Body faces must be perpendicular to tube ends



Allowances for fasteners and clearance for diaphragm maintenance



Machined from solid, Saunders Bio-Block often replaces several valves and thus result in a large single assembly that may require structural supports



Rule of thumb - Saunders Bio-Block options generally have $\frac{2}{3}$ the total wetted area of individual valves welded into a cluster or manifold

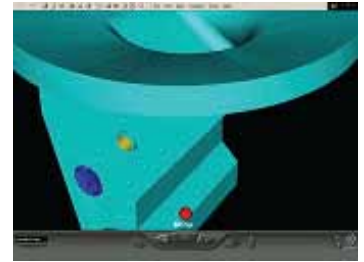
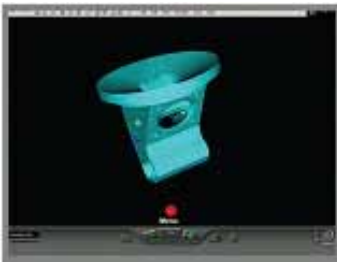


1.4 Glossary of Terms

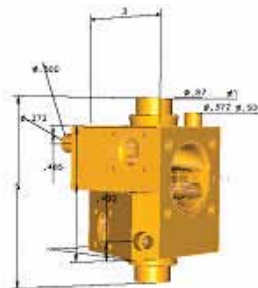
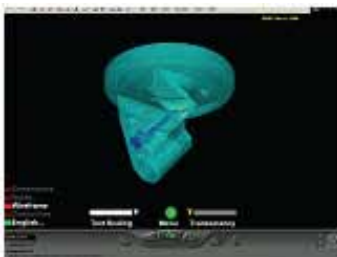
Angled Valve	Valve with inlet and outlet in different planes
Autoweld end	Tube end with weld chemistry per ASME BPE table DT-3 and with ends long enough for orbital welding
Bio-block	CPFT term for our custom machined from solid valve solutions
Branch	Secondary process line
CCBV	Angled valve with three ports in T configuration
Chamber	Valve bore adjacent to weir
Chromotagraphy Valve	Multi-port valve that has a weir in the center of a cluster to control flow through entire assembly
Clamp End	Hygienic mechanical joint
Common Chamber	Valve bore shared by more than one weir
Condensate Valve	Secondary valve sharing chamber with primary valve, located at low point of chamber used to drain chamber or primary line
Controlled Inlet Valve	Compound valve that has one weir ahead of multiple weir cluster
Virtual Reality Modelling Language (VRML)	3D visual reality utility used by CPFT to demonstrate custom SaundersBio-Block designs
Dead Leg	Wetted area of valve not subject to flow during normal operation of valve
Feeder line	Secondary process line
Horizontal Valve	Valve with inlet and outlet ports in horizontal plane
Inclined Weir	Weir rotated to permit fluid to pass over weir and drain associated valve bores
Machined from solid	Valve body produced from a single bar or billet without internal fabrication welds
Machined Tandem Valve	Machined access valve, generally two weirs and three ports
Main line	Primary process line
Multi-port Valve	Assembly with multiple weirs sharing a common chamber
Sample Weir	Secondary valve sharing chamber with primary valve, used to draw fluid from primary valve or primary line
Serial Weir	Two weirs in series with common chamber
Sterile Barrier	Serial weir design with steam supply and condensate drain weirs machined into common chamber
Vertical Valve	Valve with inlet and outlet ports in vertical plane
Weir	Dam located at 90 degrees to flow that forms differential with diaphragm
Zero Dead Leg Valve	Angled valve with three ports in T configuration

1.5 VRML - Virtual Reality Tool

We use 3D VRML files to communicate with our customers during the selection process for custom Saunders Bio-Block designs. Our engineers extract a portion of a proposed design and convert this into a smaller, e-mailable file that can be easily viewed and manipulated by our customers via their internet browser.



The VRML file offers a 3D image of the proposed design with seven pre-defined views and the ability to free rotate the image, zoom in/out and move the image across the screen. Optional wire frame, dimensioned and sectioned are also available.



1.6 Saunders Bio-Block Valves

- Saunders HC4 Bio-Block Valves are available manufactured from 316L, 1.4435, AL6XN, Hastelloy, Titanium and other alloys as required
- Saunders HC4 Bio-Block Valves can be produced with hygienic clamp or autoweld end connections in any tube specification as required. Autoweld ends have controlled sulphur per ASME BPE table DT-3 for optimum weld chemistry
- Saunders HC4 Bio-Block Valves offer full material traceability of wetted components
- Saunders HC4 Bio-Block Valves are available in a full range of mechanical and electropolished finishes
- Saunders HC4 Bio-Block Valves use standard Saunders manual and pneumatic actuators and accessories
- Bio-Block Valves use standard Saunders FDA conforming, USP V & VI tested and certified, lot traceable diaphragms. All diaphragms within the range are certified ADCF (Animal Derivative Component Free)

SECTION 2

HC4 Bio-Block Selection

- 2.1 Bio-Block Selection Process
- 2.2 Symbol Glossary
- 2.3 Bio-Block Selection / Coding
- 2.4 Bio-Block Enquiry Checklist

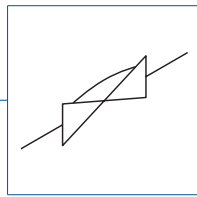
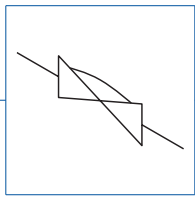
2.1 Bio-Block Selection Process

Bio-Block selection is the translation of a complex piping design into a machined from solid valve incorporating all of the required process functions into a single solution.

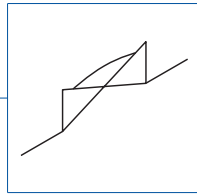
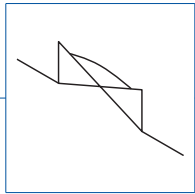
Even the most complex Saunders Bio-Block valves fall into a general configuration based on the key technology employed in the design: Zero deadleg, Serial, Multiple or Tank Weir. Common to all of these variations is the modification of one chamber of the basic diaphragm valve design into a chamber which is common to a process line, a tank or one or more additional valves. This technology eliminates a fitting and or a length of tube thus reducing dead zones and total wetted area versus a similar fabricated design.

Our Bio-Block categories are offered to help our customers understand the basic variations in technology and design available. They are also offered to assist in communicating design requirements. Saunders Bio-Block categories do not represent the entire universe of options available - many of which are compound types incorporating two or more variations into a single assembly.

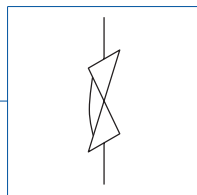
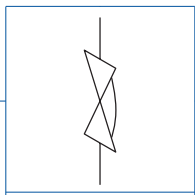
2.2 Symbol Glossary



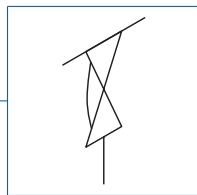
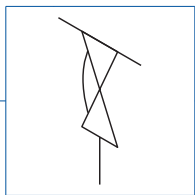
Horizontal body not at drain angle



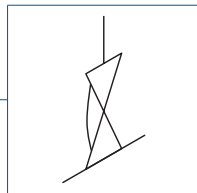
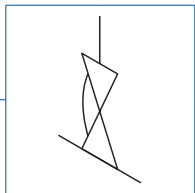
Horizontal body at drain angle



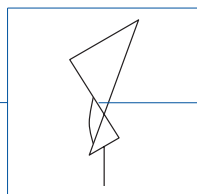
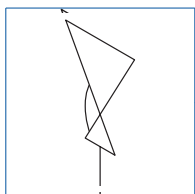
Vertical Body



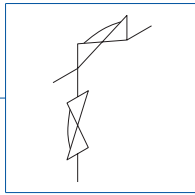
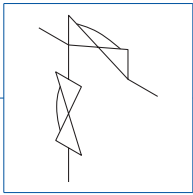
Horizontal mainline vertical weir at drain



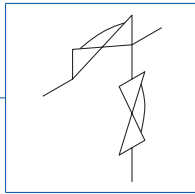
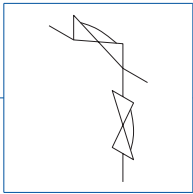
Horizontal mainline vertical weir feed-in



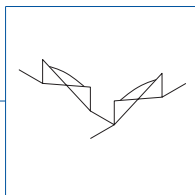
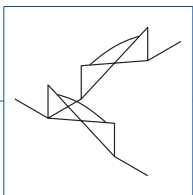
Tank bottom body



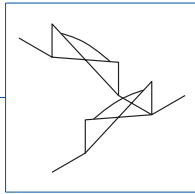
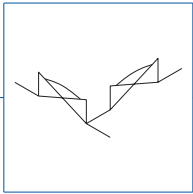
Horizontal mainline at drain
 upstream vertical tandem



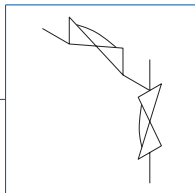
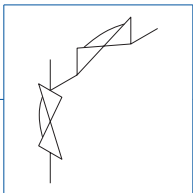
Horizontal mainline at drain
 downstream vertical tandem



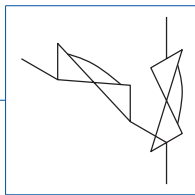
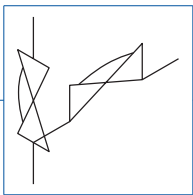
Horizontal mainline at drain
 upstream horizontal tandem at
 drain



Horizontal mainline at drain
 downstream horizontal tandem at
 drain



Vertical mainline upstream
 horizontal tandem at drain



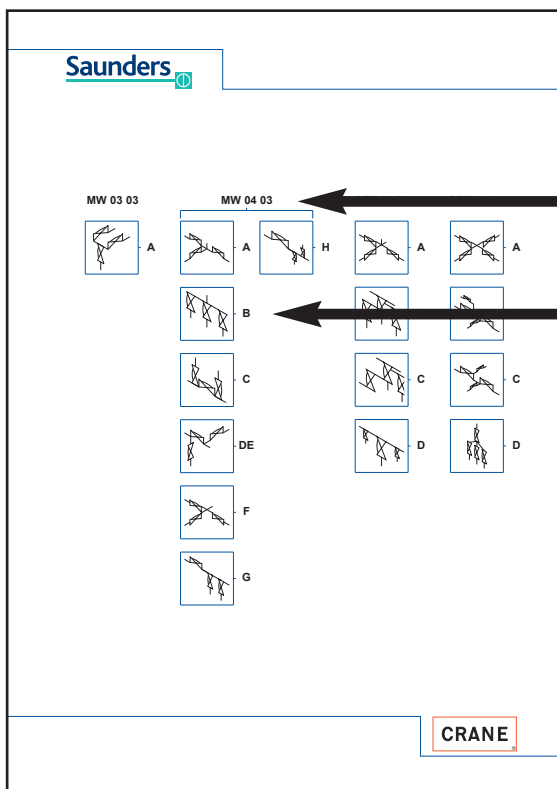
Vertical mainline downstream
 tandem at drain

2.3 Selecting Machined from Solid Valve Solutions

Using the Bio-Block Manual

Refer to P&ID image, sketch or other type of flow diagram:

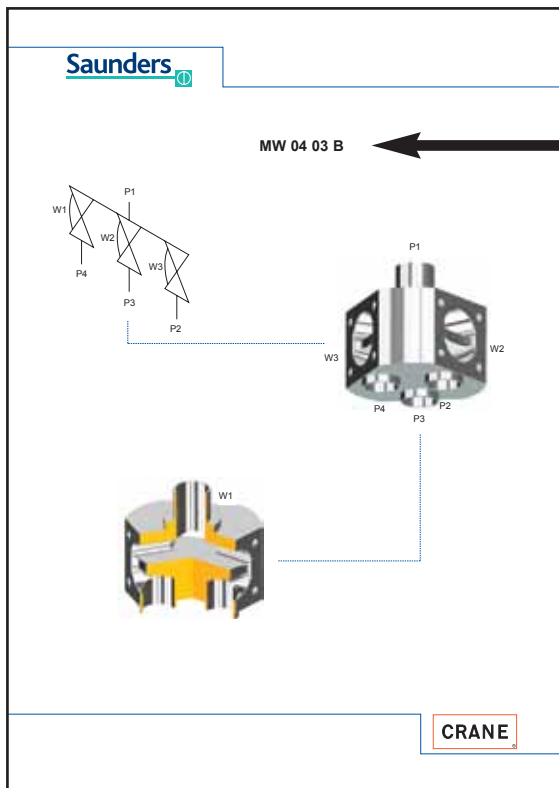
Look through the P&ID Coding Index. Note that the selections are divided by basic categories into **AW** - Aseptic Weir, **ZW** - ZeroDeadleg Weir, **SW** - Serial Weir, **MW** - Multiple Weir and **TW** - Tank Weir.



1. Compare flow diagram with examples in the P&ID Coding section of the Bio-Block Manual. It helps to search by basic type and configuration.

2. Each category of Bio-Blocks is organized by number of ports and number of weirs.

3. When a Bio-Block is found that corresponds to the requirement of the flow diagram, note the category, weir port numbers and orientation codes - in this case the category is MW (Multiple Weir), with 4 ports and 3 weirs, in the B orientation. The model number for this Bio-Block is **MW 04 03 B**.



4. Go to **MW 04 03 B** in the Bio-Block Manual and confirm the selection. The example will include P&ID diagram, 3D image and sectioned views.

5. Note that the ports are identified by alpha-numeric codes. Complete Bio-Block data sheet by indicating size of ports and end connections, weir sizes and type of actuators required for each port and weir.

In some designs, port and weir sizes may be different.

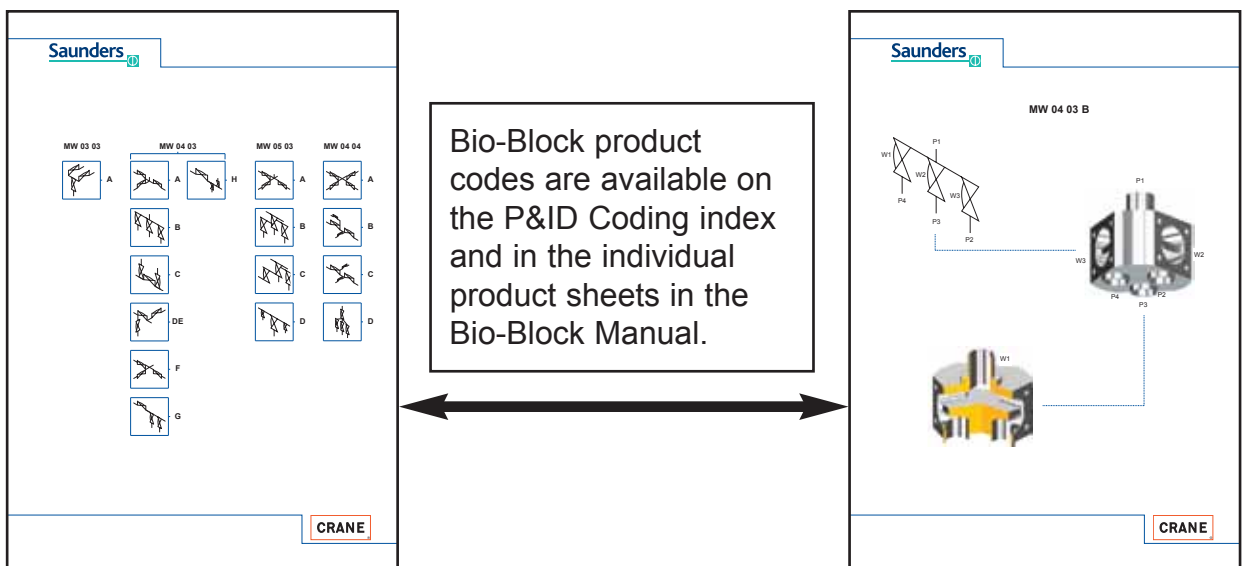
The data sheet is complete when surface finish and diaphragm requirements are added.

Saunders application specialists are available to assist in the selection of the optimum Bio-Block design. Please contact your Saunders distributor or local Saunders Sales office.

Selecting and Ordering Bio-Blocks

Is the design in the Bio-Block Manual?

If yes proceed with the following steps, if not refer to the selection guide on the following page.



1. Bio-Block Code
2. Line number, Size, End Type, Weir Number and Size and Topworks

Port Number	Line Size	End Type

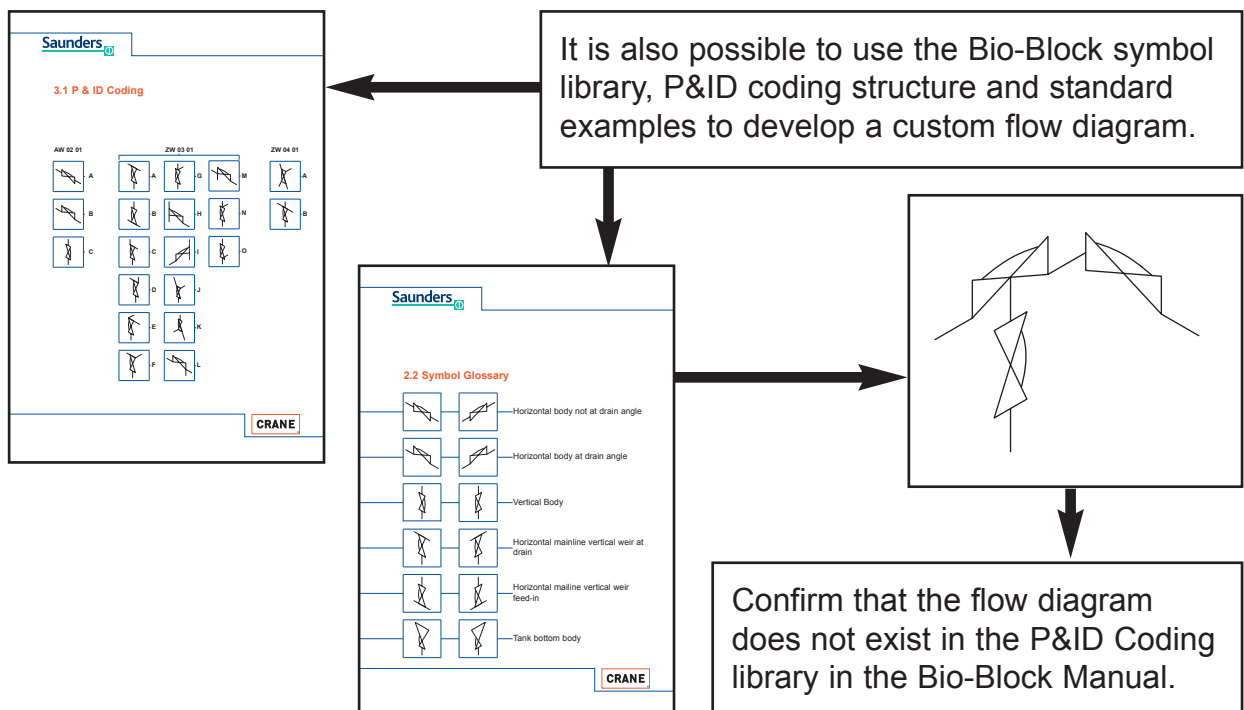
Weir Number	Weir Size	Diaphragm Type	Topworks

3. Surface Finish _____

4. Material Specification 316L
 1.4435
 Other - please specify _____

When the solution is not in the Bio-Block Manual

Not every possible Bio-Block solution is listed in the Saunders Bio-Block Manual. Some designs are compound types that combine two or more existing types of configuration into a single Block. Other designs have orientations of weirs and or porting that is not currently catalogued. If you cannot identify the ideal solution to your application, contact your local Saunders distributor or sales office for assistance and to confirm that you are using the current release of the Saunders Bio-Block Manual.



Key design elements must be considered when configuring a Bio-Block.

- Number of ports and weirs
- Piping orientation - vertical, horizontal or mixed
- Weir orientation - vertical, horizontal or mixed
- Which weirs share common chambers
- Do weirs have to fully drain
- Weirs located on the same or opposite side of centerline

Remember that not all proposed Bio-Block solutions can be manufactured. Refer to the Bio-Block preface for design rules and constraints.

Tool for Selecting and Ordering Bio-Blocks

Complete the following

1. Diaphragm type _____
2. Surface finish _____
3. Reference or tag number _____
4. Material specification 316L
 1.4435
 Other - please specify _____
5. Method of operation
6. Attach any relevant drawings, sketches and/or flow diagrams.
If none is available, fill in flow diagram in following box. Refer to symbol glossary.

Saunders application specialists are available to assist in the selection of the optimum Bio-Block design. Please contact your Saunders distributor or local Saunders Sales office.

2.4 Bio-Block Enquiry Checklist

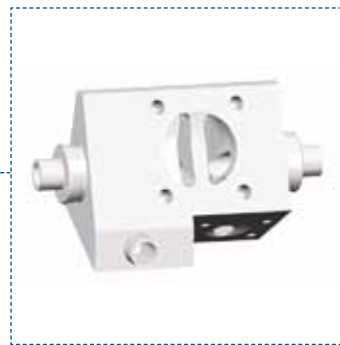
Key questions to clarify at enquiry stage or initial customer interface

1.

Is the product configuration required as a machined Bio Block construction or is a fabricated solution required by the customer?



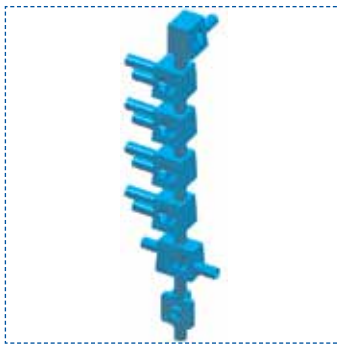
Fabricated



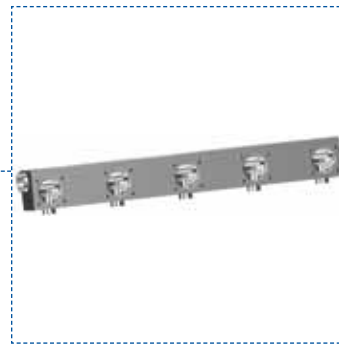
Machined Bio-Block

2.

Where a manifold assembly is specified can we look at the possibility of using a 'building block' approach i.e. using several Bio Blocks and welding tube to tube? or alternatively does the product need to be one single Bio Block machined solution?



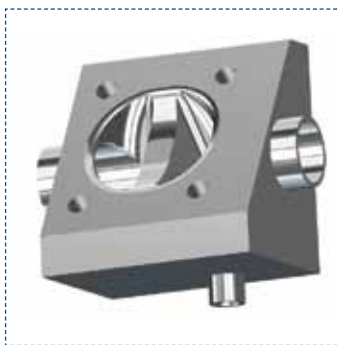
Fabricated Bio-Block



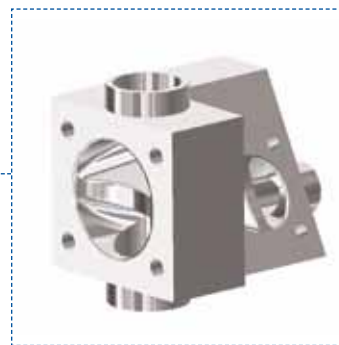
Machined Bio-Block

3.

Orientation of main line - horizontal or vertical?

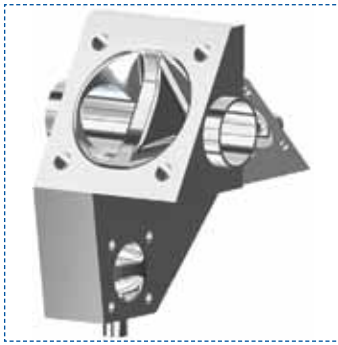


Horizontal

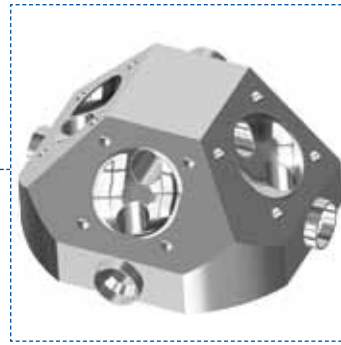


Vertical

4.
Is full drainability required for the application?

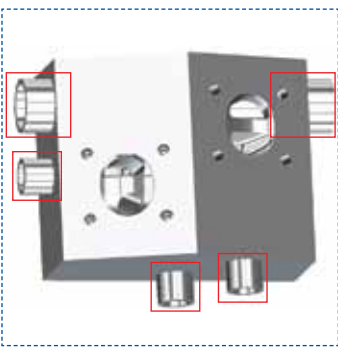


Drainable

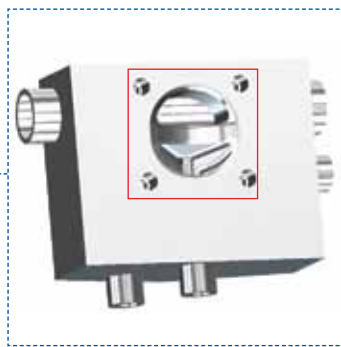


Non-drainable

5.
Please ensure all weir sizes are specified?

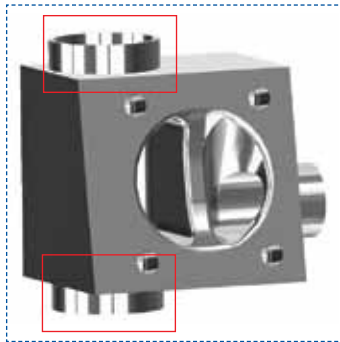


Port Sizes

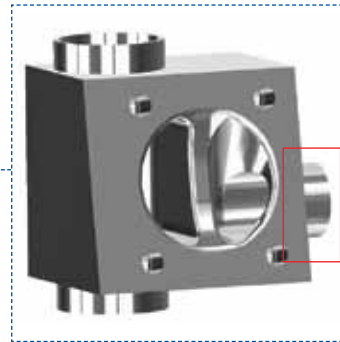


Weir Sizes

6.
What are the main line and branch sizes? Please specify



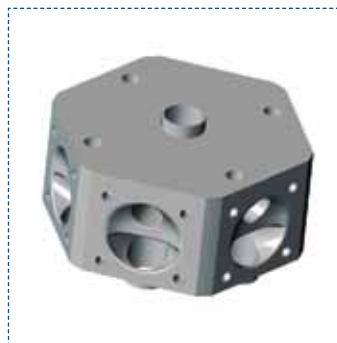
Mainline



Branch

7.
Are there any specific dimensional constraints that we have to take into account with the product design? If so please specify

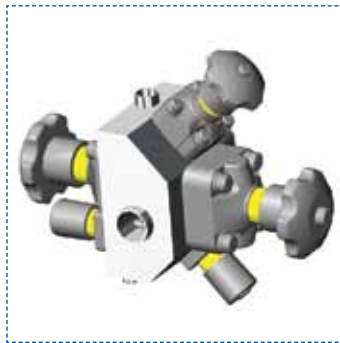
8.
Dependent upon number of weirs and size there may be a need for structural support (due to weight) - we can accommodate this in several ways during the design stage of the product and should discuss as early as possible



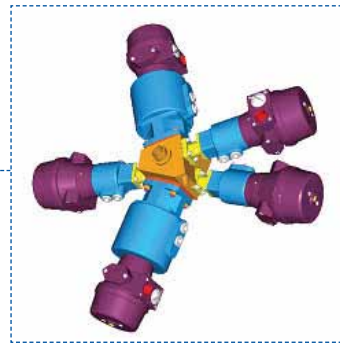
9.

What is the method of operation - manual/actuated/accessories?

This always has design implications for the physical block size and should also be known at enquiry stage.



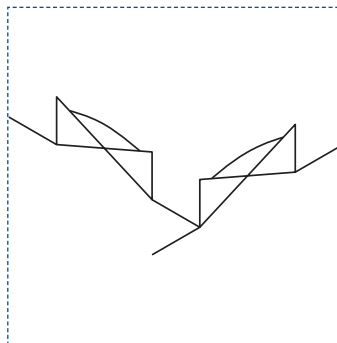
Manual



Actuated

10.

If possible either P & ID or sketch should be supplied to help clarify customer requirement



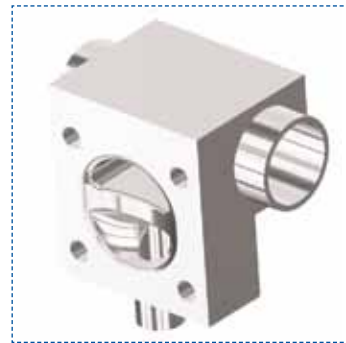
11.

Use and adoption of Bio-Block coding should be encouraged as much as possible - on the spot clarification with the Drawing office is always readily available

P & ID Key

Typical Product Code = **ZW 03 01 A**

- ZW = Product Group Type
- 03 = Number of Outlets
- 01 = Number of Weirs
- A = Orientation Type



12.

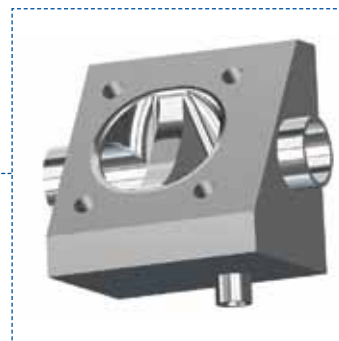
Sometimes a product orientation may be required with weir faces all in the same plane either for ease of operation or because of dimensional considerations in the system (this type of orientation will always significantly increase the deadleg of a given design. To reduce the deadleg to a minimum and also offer the most compact block arrangement it is always preferable to supply Bio Blocks of this configuration with 'back to back' weirs if acceptable to the customer. Examples shown below.



Weir in same plane



Weirs back to back



Weirs back to back