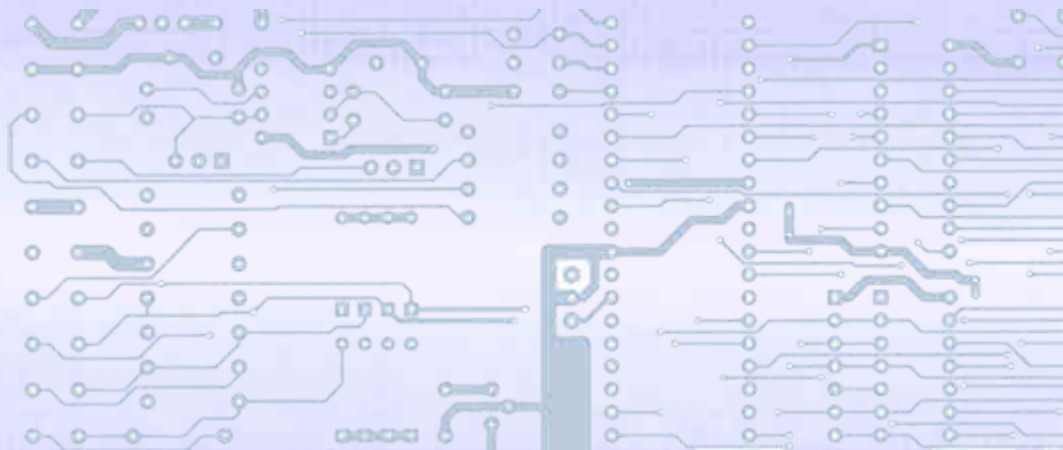
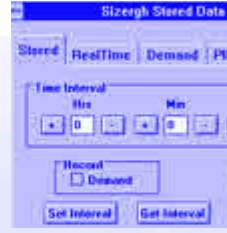
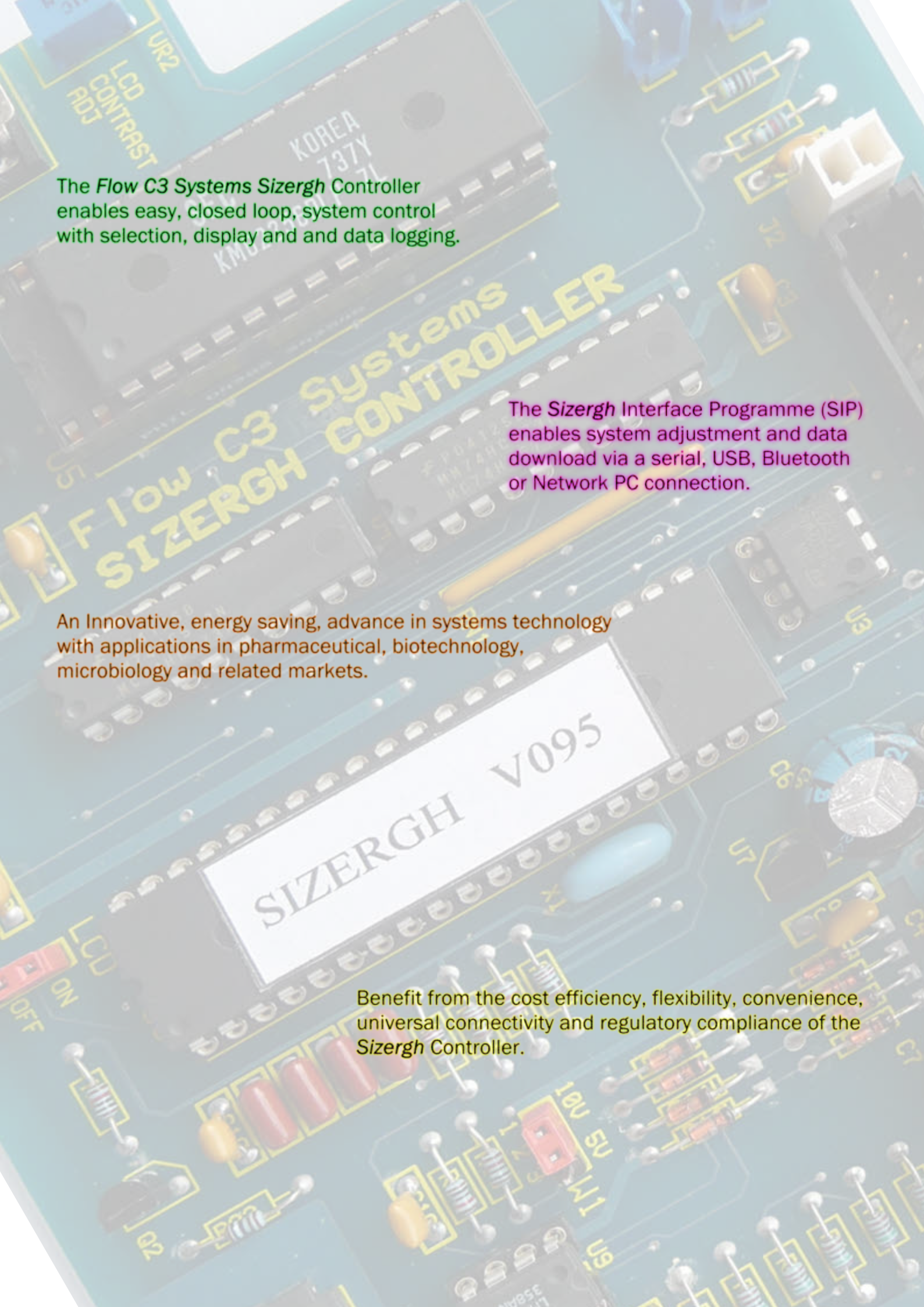


Sizegh

The Sizegh Controller

A Patented, Advanced, Closed Loop controller and Interface Programme (SIP) for a wide range of Industries. Not trying for World domination, but to Provide simple Customer Value and Benefit





The *Flow C3 Systems Sizergh* Controller enables easy, closed loop, system control with selection, display and and data logging.

The *Sizergh* Interface Programme (SIP) enables system adjustment and data download via a serial, USB, Bluetooth or Network PC connection.

An Innovative, energy saving, advance in systems technology with applications in pharmaceutical, biotechnology, microbiology and related markets.

Benefit from the cost efficiency, flexibility, convenience, universal connectivity and regulatory compliance of the *Sizergh* Controller.

The **Sizergh** controller integrates with the latest technology AC and DC fans, motors, sensors, CCF and HAF filter media to enable new, low energy systems. The innovative CCF/HAF filter unit has the ability to break down bacteria, viruses moulds and volatile organic compounds to harmless products, as well as to filter out fine particulates. The systems may be freestanding or integrated with a PC interface. Each system displays and records selected and achieved performance e.g. flow or pressure. Simultaneous control of two fans in series is easy.

The **Sizergh** Interface Programme (SIP) runs on a PC running either Windows or Linux and communicates via the controller serial port. The SIP can be used to adjust the set point, select what is recorded, alter data logging rate and the controller dynamics. Logged .csv data can be printed, saved and e-mailed to SIP or spreadsheet programmes for analysis.

The DBVM Clean Tent Reference Design features **Sizergh** Controllers and CCF/HAF filter units. DBVM Clean Tent flexible isolators provide isolation and selectable under or over pressures and/or selectable flows and a clean internal environment. The filter DeltaP is an order of magnitude less than HEPA filters which ensures incredibly low energy consumption. The **Sizergh** controller performance records can be downloaded to a PC as required.

Application features:

Fine flow and pressure control using true PID (Not error stepping) closed loop control with wide turn down ratio 20:1 (Max to Min selection).

User selected, single or multiple controllers from one PC for real time control of systems, processes and plant.

Elimination of the need for lengthy validation of PLC control software changes.

Data logging of control level history for compliance with regulatory requirements.

A paper record of systems performance is easily generated via a computer interrogating the controller.

The records of a systems working remotely can be taken and e-mailed for analysis. All software to enable this is available.

Performance verification of systems, processes and plant using inbuilt sensors.

User selected variable system response to give a faster or slower system response to changed demand selections.

Visual display of achieved systems, processes and plant performance levels.

Filter pressure loss measurement for filter replacement control.

A simplified visual readout of system pressure is available without necessarily resorting to an additional differential pressure gauge.

Stable, simultaneous flow and pressure control easily achieved.

DBVM Clean Tents can be changed from Class 1 (over pressure) to Class 2 (under pressure) (or 2 to 1) on site and run at 60 Watts max total power per cu m.

Naturally, traditional barrier isolators can also be designed to higher pressures in the 70 - 250 Pa pressure range and clean rooms at pressures as required to suit the application.

The HAF filter media run at up to 3 m/s - hot wire anemometry sensors, measuring from 0.4 to 5 m/s, may be used to interface to the **Sizergh** controller.

Certification features:

The **Sizergh** controller carries full **CE** certification, validated by a Technical Construction file. System builders may access this and other material by negotiation.

The **Sizergh** controller can comply with **ATEX** regulations. This is by use of a dust proof enclosure to IP 65 which itself has passed **ATEX** testing. Additionally, although there are no ignition sources on the **Sizergh** controller board, this enclosure is filled with mica particles. This ensures that any internal flame propagation is impossible.

Any product with electronic data logging records has to be considered against 21 CFR Part 11. The **Sizergh** controller is exempt from

having to comply with 21 CFR Part 11:

1. If the record of the system performance, in the form of a .csv file, is printed off a computer, as an intermediate paper record.
2. If the record of the system performance, in the form of a .csv file, is exported to a computer for analysis in other programmes and ultimate print out.

Because the following exemptions from 21 CFR Part 11 apply:

"On the other hand, when persons use computers to generate paper printouts of electronic records, and those paper records meet all the requirements of the applicable predicate rules and persons rely on the paper records to perform their regulated

activities, FDA would generally not consider persons to be "using electronic records in lieu of paper records" under §§ 11.2(a) and 11.2(b). In these instances, the use of computer systems in the generation of paper records would not trigger part 11."

"On the other hand, records (and any associated signatures) that are not required to be retained under predicate rules, but that are nonetheless maintained in electronic format, are not part 11 records."

"However, a record that is not itself submitted, but is used in generating a submission, is not a part 11 record unless it is otherwise required to be maintained under a predicate rule and it is maintained in electronic format."

The source of this guidance is: B. Details of Approach - Scope of Part 11, 1. Narrow Interpretation of Scope, 2. Definition of Part 11 Records to be found in: Guidance for Industry Part 11, Electronic Records; Electronic Signatures - Scope and Application U.S. Department of Health and Human Services Food and Drug Administration.

Consider the Commercial benefits of the **Flow C³ Systems Sizergh™** Controller....

Cost efficiency (Use only the components that the system needs)

Flexibility (9-24V sensors)

Convenience (Free-standing or local / remote PC connectivity)

Near universal connectivity (AC and DC fans, motors, pumps or loads)

Regulatory compliance (Control and multi-channel logging; CE, ATEX, 21 CFR part 11)

....and Contact us.

For Sales and Warranty of the **Sizergh™** Controller contact:
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E-Mail: dan.baxter@baxpro.co.uk

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Telephone +44 (0)1260 253637 Mobile: +44 (0)7841 436363
E-Mail: mail@c3sys.co.uk