

## **Devices, Data & Operational Efficiency** Getting the Most from Bioprocess Equipment

**Ken Clapp,** Sr. Bioreactor Technology, Application & Integration Leader, Cytiva **Joe Sipka,** Global Business Development, Brooks Instrument



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## Introduction

This is the third paper in a series discussing intelligent, data-rich devices, a.k.a, industrial internet of things (IIoT) devices, in bioprocessing.

The first paper, Using Digital MFC Diagnostic Capabilities to Improve Bioprocessing Results. discussed the impact of modern-day mass flow control devices, with their highly integrated microprocessor-based electronics, on bioprocess equipment design. The capabilities of these devices, due both to their electronic hardware and the supporting firmware, offer more than just gas delivery. These devices now possess native "intelligent" functionality associated with the industrial internet of things (IIoT), namely, data management and connectivity. This functionality can be used to improve or enhance biomanufacturing operational efficiency but requires a new level of collaboration between component suppliers, equipment manufacturers and drug makers.

The second paper, *Satisfying the Increasing Need for Flexibility in Bioprocess Equipment,* discussed how the shifting biotherapeutics landscape requires adaptability down to the components and devices used in building bioreactors. A mass flow controller design and performance level that supports enhanced equipment flexibility was presented.

Using gas mass flow controllers (MFCs) which are critical components of the bioreactor, this paper continues the discussion, focusing on the use of data in the broader scope of Industry 4.0 data. Also known as the <sup>1</sup>Fourth Industrial Revolution, Industry 4.0 encompasses four foundational types of disruptive technologies:

- 1. Connectivity, Data, Computational Power
- 2. Analytics and Intelligence
- 3. Automation
- 4. Advanced Manufacturing Technology

We will continue using previously established device data categories (pedigree, performance, reliability) relevant to the three essential stakeholders (device manufacturer, equipment manufacturer, drug maker). Process data will be added, to broaden the discussion.

For data to have value, it must be useful in decision-making. We will apply a typical knowledge management concept, the knowledge pyramid, for this purpose. The concept of a device "fingerprint" will be introduced and discussed using a radar graph, along with methods to review contextualized data sets. With these new concepts in mind, we will provide representative examples, using a Brooks Instrument Biotech MFC, as the IIoT device, and the bioreactor, as the unit operation. Using representative component and process data streaming from the bioreactor, we intend to show how categorization organizes and establishes context. The examples will show that contextualized data possess meaning which, in turn, supports knowledge creation. Knowledge, plus insight, establishes domain expertise, or wisdom.

<sup>1</sup>McKinsey & Company, What are Industry 4.0, the Fourth Industrial Revolution, and 4IR?, Aug 17, 2022 (https://www.mckinsey.com/featured-insights/mckinsey-explainers/what-are-industry-4-0-the-fourth-industrial-revolution-and-4ir)

# Data, Knowledge Management and Domain Expertise

### Data

Across industry sectors, Industry 4.0 is expected to continually transform businesses through data, analytics, and automation. Data is central to the benefits associated with Industry 4.0 and is crucial for on-going industrial progress, operational efficiency, better and more consistent product quality, and greater product yields. Biopharma 4.0 is a term coined to represent the industrial revolution in biopharmaceutical manufacturing. A comprehensive approach to data use appears to be lagging other industries. <sup>2</sup>Biophorum Operations Group has outlined the digital plant maturity model (DPMM) associated with biopharmaceutical manufacturing. The general state of production plants in the industry, today, can be characterized as 'digital silos' – disconnected sources of data which are part of a larger biomanufacturing environment. Siloed data is evidence there is a need for a comprehensive approach to data characterization, knowledge management, and unit operation design.

<b>Maturity Level</b>	Level Name	Description		
1	pre-digital plant	manual, paper-based processes		
2	digital silos	'islands of automation'		
3	connected plant	high level of automation, integration and systems standardization		
4	predictive plant	integrated plant network, pervasive real-time predictive analytics		
5	adaptive plant	'plant of the future,' autonomous, self-optimizing, plug-and-play		

#### Figure 1 - Digital Plant Maturity Levels

### **Knowledge Management**

IIoT devices generate data. Data may be component-specific only. It also may include relevant process data, like temperature, or gas flow rate, etc. Data forms the base of a knowledge management pyramid. Applying the Data, Information, Knowledge, Wisdom (DIKW) pyramid to a unit operation, data can be categorized broadly, into device and process. Previously, we had categorized device data into pedigree, performance, and reliability. Process measurement data (e.g., Temperature, RPM, pH, etc.) could be expanded to include off-line measurements. For this discussion, in-situ process measurements only are considered.

# Data, Knowledge Management and Domain Expertise

These various data, categorized relative to the bioreactor, impart context. Contextualization turns the raw data into information, useful as we move further up the pyramid. Conceptualizing, comparing, and synthesizing the information creates meaning. With meaning comes knowledge about equipment and bioprocess. Two more levels of the pyramid were built. Armed with knowledge, a domain expert can gain relevant insight. We have reached the pyramid's top - wisdom. This wisdom may be used in decision-making and actions in specific scenarios, e.g., troubleshooting, process optimization, etc.

### **Domain Expertise**

Figure 2 is a representative knowledge management pyramid for mass flow controllers integrated into a bioreactor. This single pyramid reflects the integration of each stakeholder's domain expertise and core competencies, from raw data to decision-making capabilities, across components, equipment, and drug manufacturing.





# Stakeholder Domain Expertise Transition, from Device to Bioprocess

With the integrated perspective about drug making, Figure 3 shows how the domain expertise shifts, from device design, through bioreactor integration, to use in bioprocess, based on stakeholder function.

Depicted here on the Y-axis are the three main stakeholders (end user, equipment manufacturer and process instrument manufacturer). The magnitude of bars represents their relative domain expertise among process, system, and instrument categories.



Domain Expertise by Key Stakeholder

Differences arise from the attributes each stakeholder may select relative to their domain expertise. As the device manufacturer, the domain expertise of Brooks Instrument centers around the device itself, whereas the drug maker's end user expertise is associated with the bioprocess. The equipment manufacturer bridges both domains, possessing a level of expertise in both.

Figure 3

## **Fingerprint Data Explanation**

A representative fingerprint has been included below in support of scenario F1. The graphic depiction is a human readable format using a subset of MFC attributes for that specific example. The approach can be applied to any of the other scenarios, as needed. A visual depiction may be easier to understand than a list of attributes, for quick insight and timely decision-making. Device data subsets and fingerprints may differ between device manufacturer, equipment manufacturer or drug maker.



A contextualized set of MFC attributes are shown at the perimeter of the radar graph, with values ranging from 0-5. The color-coded lines represent three distinct fingerprints:

- 1. Baseline, or known good;
- 2. Warning, where a sufficient number of attributes may indicate problems;
- 3. Alarm, when action is necessary.

## **Fingerprint Data Explanation**

Fingerprint Data	MFC Data Attributes
Response Time	Flow Output, MFC Setpoint, Time
Valve Leak-by	Flow Output, MFC Setpoint, Time
Temperature	Temperature
Output Noise	Flow Output, MFC Setpoint, Valve Position, Time
Valve Drive	Valve Position, Time
Input Power Supply	Input Power Supply
Zero Output	Flow Output, MFC Setpoint, Zero Array

Considering pedigree, performance and reliability categories, certain attributes can be combined, from within or across categories. Comparing the same fingerprint, over time, may provide a quick visual reference for attributes that have changed. Fingerprint differences may then be used to identify process anomalies, diagnose component or equipment failures, or trigger routine maintenance events. The collection of attributes shown in the fingerprint can be used to troubleshoot oscillating dissolved oxygen values.

This section will present some practical scenarios, highlighting key MFC attributes worth consideration, which may be useful to one or more stakeholders (See "Referenced Scenarios" in Appendix A for a full list of suitable attributes). The scenarios begin with the manufacture of the MFC, includes device incorporation into the bioreactor, touches on metrology and maintenance, and concludes with two process-related scenarios.

A. Manufacturing & Quality Assurance

- B. Configuration & Integration
- C. Installation Qualification
- D. Routine Metrology
- E. Predictive Maintenance
- F. End User Scenario
  - 1. Dissolved oxygen reading is erratic; uses health and performance data
  - Dissolved oxygen level cannot reach setpoint (too low); uses health and performance data



#### A. Manufacturing & Quality Assurance

Digital attributes play a crucial role in the quality and manufacturing processes associated with the Brooks Instrument Biotech MFC. All 500+ attributes will be utilized by Brooks Instrument during the manufacturing process, setting and verifying them to ensure the device is configured to work properly within the bioreactor being built by the equipment manufacturer. Appendix A is a sample of the attributes utilized by various domain experts and the category (pedigree, performance, and reliability). Brooks Instrument production calibration stations automatically set the reference temperature (pedigree data type) during critical linearization and accuracy processing steps. An end-of-line process check executed by the Quality inspector at Brooks Instrument ensures each device is built to product and order specifications, e.g., "process flow", and verifies attributes have been set correctly.



#### **B.** Configuration & Integration

Integration of an intelligent device into a subsystem or system has two fundamental steps:

- 1. Design
- 2. Configuration

Design has been discussed previously (paper 1). Configuration is the practical step of setting up the component to work within the system, contributing to the integrated functionality, including with the automation platform and for the bioprocess application. Brooks Instrument Biotech MFC integration within a bioreactor considers the MFC's measurement and control functionality. At first glance, this would be the MFC's role in controlling dissolved oxygen, pH or excess metabolic CO<sub>2</sub> through the flow of specific gases. Performance and pedigree attributes immediately come to mind here, such as "Flow Units", "MFC Setpoint" and "Flow Totalizer". From overall gas flow management functionality perspective, it makes sense these three attributes represent the three attribute categories, pedigree, performance, and reliability, respectively.

Beyond this initial consideration, there are attributes useful in bioreactor manufacturability, from one or more categories. At the equipment manufacturer, the pedigree information along with the MFC product documentation become integral parts of an incoming examination process, confirming the device(s) ordered were the devices received. MFC pedigree attribute ("Full\_Scale Process Gas", "Serial Number", "Flow Units", etc.) can be recorded in an ERP system, establishing a digital data trail, from incoming examination, through testing and shipment of the finished bioreactor. Attributes like "IP Address", "Network Mask", "pgGasStandardNumber" and "Calibration Instance" are useful in configuring each MFC for its location and use relative to the P&ID.

Looking further into the MFCs, several attributes are available to improve serviceability. Within the reliability (health) category, there are attributes (e.g., "Valve\_Position", "Power On Hours") that when used alone, or in conjunction with pedigree and performance attributes, or process attributes, may aid the bioreactor manufacturer's in-house and field service organization to troubleshoot issues. The result includes faster root cause determination, shortened downtime and increased equipment utilization.



#### C. Installation Qualification

Only installation qualification (IQ) will be treated here. Operational and process qualifications are more involved, however, the principles discussed here can be applied there, too. Pedigree attributes play a key role in this qualification activity. For an IIoT device such as the Brooks Instrument Biotech MFC, proper installation starts with the "IP Address" and "Device\_Type"

These are used by the equipment manufacturer to establish the intelligent I/O architecture. In standardized equipment designs, addresses can be the same from system to system. "Device Type" and "Serial Number", "Tag Number" establish each MFC as a uniquely identifiable device and combined with "Calibration Date" these data also may be used to register the device's routine metrology cycle. The owner can compare this direct device data against the bioreactor product documentation to verify the device and equipment have been properly manufactured, installed, and configured.



#### **D. Routine Metrology**

Routine maintenance and recalibration can be burdensome, time-consuming and disruptive for the drug maker. Conventional (non-intelligent) MFCs do not offer attribute data associated with pedigree, performance, or reliability, requiring separate tracking of service and recalibration dates, and no inherent functionality to aid in troubleshooting. Bioreactors, incorporating data-rich components, like the Brooks Instrument Biotech MFC enable a more intelligent method of metrology management.

The common calibration approach based on time, or schedule is supported by "Calibration\_Due" and is trackable by "Serial Number". To implement a usage-based metrology approach, MFC attributes such as "Total\_Flow\_Hours", "Power On Hours" and "Active\_Alarm\_Status" are available.



#### E. Predictive Maintenance

A typical installation issue is an unintended restriction of the inlet pressure to the gas MFC. This could result in a slower growth rate or scrapping the batch. Brooks Instrument Biotech MFCs will report a "restricted flow" that could be integrated into the control system. Automatically adjusting the regulator to the required pressure, verifying upstream valves are operational and opened, and verifying the state of the facility gas-delivery systems (valve manifold box) are examples of actions based on this MFC feedback. If the inlet pressure is not able to recover automatically, an alternative solution could be to substitute the required gas flow via another MFC in the gas box. Other MFC reliability and performancebased attributes that are useful with predictive maintenance are "Zero Array", "Temperature", and "Backstreaming".

In relation to modern manufacturing operations, automation has played an increasingly important role. And, as more data is generated starting at the component level, efficiency gains are possible as data is leveraged to generate information and expand knowledge about the characteristics of the controlled process.



#### F. End User Scenario

1) A noisy dissolved oxygen value is an important example because of the criticality of a stable value for cell growth, process performance and product yield. Finding a root cause may rely on device, equipment, and process data. An erratic value may arise from a variety of sources: probe, probe cable, MFC or process. With the onset of an erratic dissolved oxygen process value, an end user may focus initial troubleshooting on the probe as the cause. Routine process sampling and analysis may provide further insight into other contributory process attributes, e.g., cell viability. Should either, or both troubleshooting efforts be inconclusive,

MFC attributes could provide information necessary to determine intermittent, or discontinuous MFC gas flow helping to determine a root cause.

Potentially useful for checking the MFC are specific attributes from Alarms and the defined categories: pedigree, performance and reliability (Health). From Alarms, "ControlErrorBand" and "WarningSettlingTime" may differentiate between a steady-state issue and an initial conditions gas flow issue, respectively. Information about the gas flow control valve can be determined from "Valve Pedestal" and "Valve Tuning", both pedigree attributes. "Valve Position", a reliability attribute also may prove useful. Evaluating this valve data along with performance category data for "Flow Output" (flow sensor value) and "MFC Setpoint" (current MFC setpoint value) could confirm if there is a problem with the MFC or if the MFC is simply reacting appropriately to other process or system issues and effectively reporting that there is an issue.

2) Another scenario that presents first to an end user as a potential process problem is the bioreactor's inability to reach the defined dissolved oxygen setpoint. Like the previous scenario, the manifestation of a problem at the process level may result from something in the growth environment or one, or more elements within the closed-loop measurement & control system. In the growth environment, it could be insufficient nutrients, too high a cellular demand for oxygen or declining cell viability. Within the measurement & control system sources may include sensors, cable, DO transmitter, valves, regulators, mass flow controller, or software. The end user must first determine if it is a process or equipment source. Perhaps the first thing checked would be the existence of any incorrect limits on gas flow rates imposed by settings in the software. Failing to be the cause, the end user next may check cell density and viability,

or nutrient levels. Should these not be the cause, attributes available within the MFC can be checked.

From among the entire set of available MFC attributes, several attributes may be especially useful. "Active Alarms" indicates one or more active alarms; "Restricted Flow" indicates the gas differential (inlet/outlet) pressure is insufficient to reach required gas flow setpoint. The latter attribute, if active, would guide a trouble-shooter to check the incoming utilities or check for damaged gas supply tubing. If the cause remains indeterminant, "Calibration\_Due" (a pedigree attribute) and "Valve Position" (a reliability attribute) may offer insight sufficient to act.

## Summary

Data is the basis of "4.0" revolutions, in any industry, including biopharma. Data is a prerequisite for analytics, insight, and automation. The burgeoning number of IIoT data-generating devices has basically filled disconnected (data) silos with more and more data. Integration of the Brooks Instrument Biotech MFC into a bioreactor and a union of their data demonstrates that a comprehensive approach, including data characterization, knowledge management and equipment design can break down these silos. Without silos, the potential of the data can be realized.

For value creation or improvement, data must support decision-making and action-taking. We used the layers of a knowledge pyramid as a metaphor for value creation. Data forms the foundation of the pyramid. Context, meaning, and insight move the data up the knowledge pyramid. Meaning and insight are gained from analysis. Along the way it becomes more useful, more valuable to the relevant stakeholders. Elevating the discussion about data to a knowledge management topic may be the necessary approach to bring the stakeholders together to further promote industry 4.0 objectives.

A radar chart was chosen to provide a graphical representation, or fingerprint of contextualized MFC data. Context came from the selection of a particular set of MFC attributes. Although, there may be other graphical representations used for the same purpose, the radar graph offered a visual tool for differentiating between normal, warning and alarm device states. The attributes chosen to construct the data set could be expanded by any given stakeholder, for their specific analytical needs. To this end, we explored seven examples. Each example offered an opportunity to conceptualize how the data could be visualized and be used for analysis. Other, more advanced methodologies, including machine learning or artificial intelligence could be applied.

For a biopharmaceutical industrial revolution to progress and achieve its objectives, there must be convergence, adoption, and integration of enabling technologies, like the Brooks Instrument Biotech MFC, within bioprocess equipment. Furthermore, there must be a comprehensive view of which data and how the chosen data can be used to influence operational efficiency, improve quality, and increase drug product yields. Improvements in data density and integration within the MFC, material certificates, and calibration certificates could be added to the device's memory. Any of this digitally traceable device data could be accessed via the bioreactor automation system, for process control, auditing, or predictive maintenance. Equipment automation systems could dynamically manipulate parameters based on process step or type, device or equipment error conditions, or bioprocess anomalies leading to faster drug releases, greater equipment utilization, improved yields and manufacturing throughput. Knowledge management, proper equipment design and stakeholder cooperation are fundamentally necessary to transform Biopharma 4.0 potential to reality.

## Appendix A

Referenced Scenarios	Data Category	Attribute Identity	Device Attribute	Description	Data Use	Stakeholder
а	Alarms	Process Control Monitoring (201)	Device_Status	Device Status	Active Monitoring	Automation/Maintenance
а	Alarms	TC-IP (245)	tcpStatus	EtherNet Communication Status	Communication	Equipment Manufacturer
a,d,f	Alarms	Process Control Monitoring (201)	Active Alarms	Active Alarms	Active Monitoring	Automation/Maintenance
a,f	Alarms	Flow Controller (158)	ControlErrorBand	Flow deviation allowed during steady state control	Configuration	Equipment Manufacturer
a,f	Alarms	Status (184)	Input Power Supply	Reports input system power supply	Service/Troubleshooting	Maintenance/Automation
а	Alarms	Flow Meter (169)	Flow_Alarm_Restricted Flow_Th	Time threshold for restricted flow event	Configuration	Process/Automation
а	Alarms	Flow Meter (169)	Flow_Alarm_Restricted Flow_L	FS threshold for restricted flow event	Configuration	Process/Automation
a,e,f	Alarms	Status (184)	Restricted Flow	Reports back if the MFC has insufficient inlet pressure to achieve the reunited setpoint	Service/Troubleshooting	Maintenance/Automation
a,f	Alarms	Flow Controller (158)	WarningSettlingTime	MFC allowed controlled time	Configuration	Equipment Manufacturer
а	Alarms	TemperatureMeter (164)	tmWarningTripPointHigh	High Temperature Alarm Trip Point	Process Recipe Change	Process/Automation
а	Alarms	Status (184)	No_Flow_Limit	No Flow Limit Threshold	Service/Troubleshooting	Automation/Process
a,d	Alarms	Status (184)	Backstreaming	Reports when a gas/liquid flows backward thru MFC	Service/Troubleshooting	Process/Automation
а	Alarms	TemperatureMeter (164)	WarningSettlingTime	Time before triggering or clearing temperature alarm	Service/Troubleshooting	Maintenance/Automation
а	Pedigree	Brooks BEST Software (Calibration Flow)	Calibration Values	MFC calibration values	Maintenance Check	Brooks Technical Support
a,b,c	Pedigree	TC-IP (245)	IP Address	TCP/IP Address	Configuration	Equipment Manufacturer
а	Pedigree	Identity (1)	Vendor_ID	ODVA Vendor ID	Configuration	Equipment Manufacturer
а	Pedigree	Flow Meter (169)	Full_Scale_Process Gas	Full scale range of the selected process gas page	Configuration	Equipment Manufacturer
a,b	Pedigree	Flow Meter (169)	Process Gas ID	Numeric identifier of the process gas page	Configuration	Equipment Manufacturer
a,b	Pedigree	Identity (1)	Serial_Number	Device Serial Number	Configuration	Equipment Manufacturer
а	Pedigree	Process Page (102)	ReferenceTemperature	Calibration reference temperature	Metrology Check	metrology
а	Pedigree	Brooks BEST Software (Valve tuning)	Valve Pedestal	Valve turning	Maintenance Check	Brooks Technical Support
a,b,c	Pedigree	TC-IP (245)	Network Mask	TCP/IP Network Mask	Configuration	Equipment Manufacturer
a,c	Pedigree	Identity (1)	Device_Type	General Product Type	Configuration	Equipment Manufacturer
a,b	Pedigree	Flow Meter (169)	Flow_Units	Flow Meter Units	Configuration	Equipment Manufacturer/ Metrology
a,b	Pedigree	Flow Meter (169)	Calibration_Instance	Selected Process Gas Instance	Configuration	Equipment Manufacturer
a,b	Pedigree	Process Page (102)	pgGasStandardNumber	Configured gas type	Configuration	Equipment Manufacturer
а	Pedigree	fmCalibrationDuelElapsedHours	Calibration_Due	Recommended recalibrated time for MFC	Metrology Check	Metrology/Automation
а	Pedigree	Process Page (102)	ReferencePressure	Calibration reference pressure	Metrology Check	Metrology
а	Pedigree	Brooks BEST Software (Valve tuning)	Valve Tuning	Valve PID settings	Maintenance Check	Brooks Technical Support
а	Performance	Process Control Monitoring (201)	Valve_Override	Current valve override setting	Maintenance Check	Maintenance/Metrology
a,c	Performance	Process Control Monitoring (201)	SafeState	Device is in executing state	Active Monitoring	Automation/Process
a-f	Performance	Process Control Monitoring (201)	Flow Output	Flow Sensor Value	Active Monitoring	Automation/Process
a-f	Performance	Process Control Monitoring (201)	MFC_Setpoint	Current setpoint value	Active Monitoring	Automation/Process
a,e,f	Performance	Process Control Monitoring (201)	Temperature	Temperature sensor value	Active Monitoring	Automation/Process
а	Performance	Flow Meter (169)	Zero Adjustment	Reports back total drift of MFC	Maintenance Check	Maintenance/Metrology
а	Performance	Brooks BEST Software (Calibration Flow)	Sensor Flow	MFC sensor flow output	Maintenance Check	Brooks Technical Support
а	Performance	Flow Meter (169)	Device Zero Enabled	Starts the device zero operation	Metrology Check	Metrology/Automation
a,f	Performance	Process Control Monitoring (201)	Finger Print	Health Index of MFC	Active Monitoring	Automation/Process
a,f	Reliability	Process Control Monitoring (201)	Valve Position	Valve Drive	Active Monitoring	Automation/Process
a,d	Reliability	Process Control Monitoring (201)	Total_Flow_Hours	Total hours of flow through flow sensor	Active Monitoring	Meterology/Process
a,e,f	Reliability	Flow Meter (169)	Zero Array	Array of zero events with flow, temperature and flow hrs.	Predictive Maintenance Check	Maintenance/Metrology
a,d	Reliability	Flow Meter (169)	Power On Hours	Total power on hours at the time of the zero operation	Maintenance Check	Maintenance/Metrology
a,b	Reliability	Process Control Monitoring (201)	Flow_Totalizer	Flow sensor totalizer	Active Monitoring	Process
а	Reliability	Flow Controller (158)	Ramp_Time	MFC response time adjustment	Configuration	Process/Automation
а	Reliability	Flow Controller (158)	Flow Setpoint Limit	Limits setpoint value sent to MFC from host	Configuration	Automation/Process

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а	Pedigree	Brooks BEST Software (Valve tuning)	Valve Pedestal	Valve tuning	Maintenance Check	Brooks Technical Support
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a,b	Pedigree	Flow Meter (169)	Flow_Units	Flow Meter Units	Configuration	Equipment Manufacturer/ Metrology
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a,e,f	Reliability	Flow Meter (169)	Zero Array	Array of zero events with flow, temperature and flow hrs.	Predictive Maintenance Check	Maintenance/Metrology
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a,b	Reliability	Process Control Monitoring (201)	Flow_Totalizer	Flow sensor totalizer	Active Monitoring	Process
а	Reliability	Flow Controller (158)	Ramp_Time	MFC response time adjustment	Configuration	Process/Automation
а	Reliability	Flow Controller (158)	Flow Setpoint Limit	Limits setpoint value sent to MFC from host	Configuration	Automation/Process

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