

Process Analytics portfolio for BioPharma

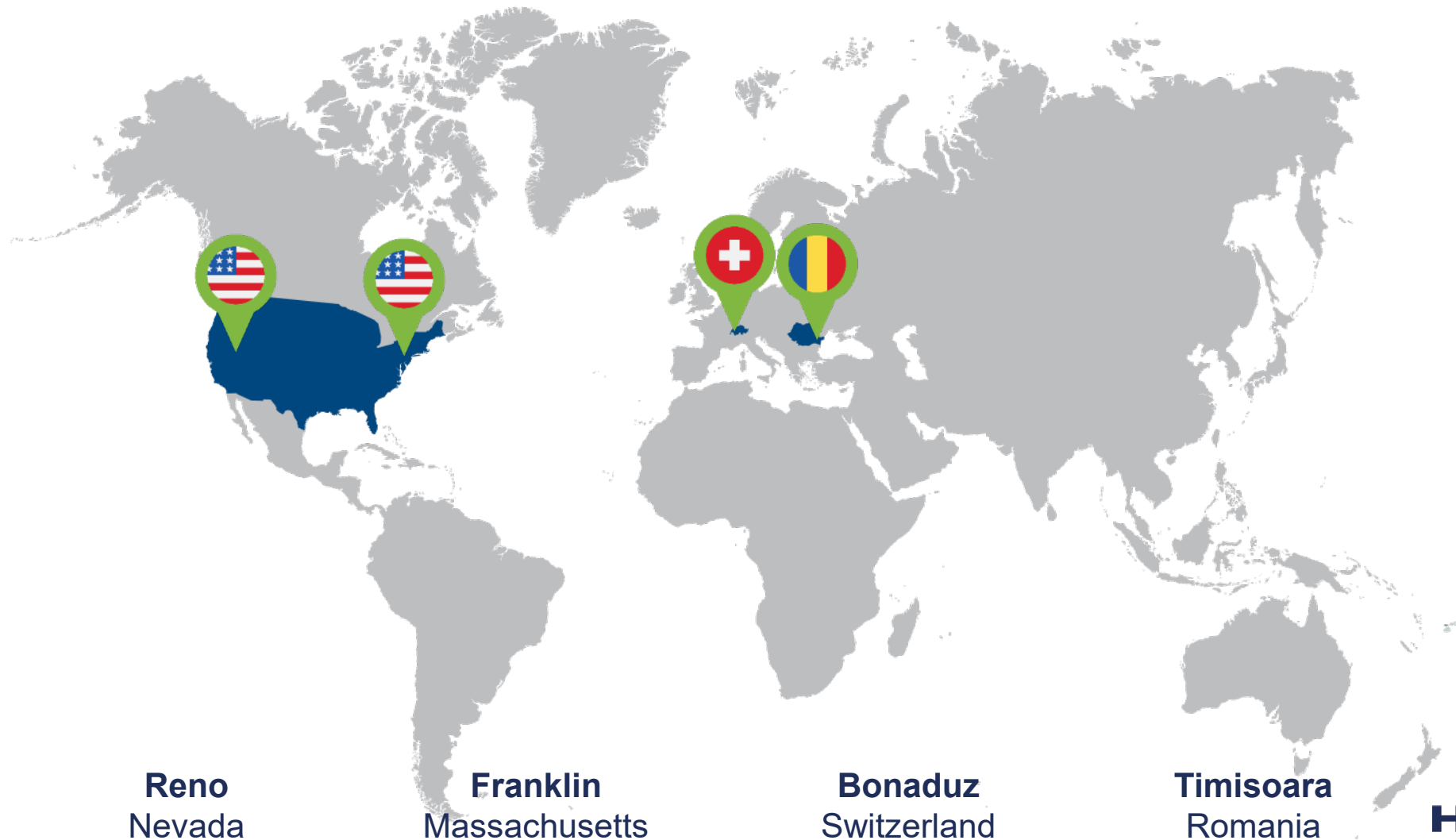


Dmitry Oleynikov

Area Sales Manager

Global Reach

4 Manufacturing Sites Across the World



30.10.2023

HAMILTON

Our Organization

Five Business Units

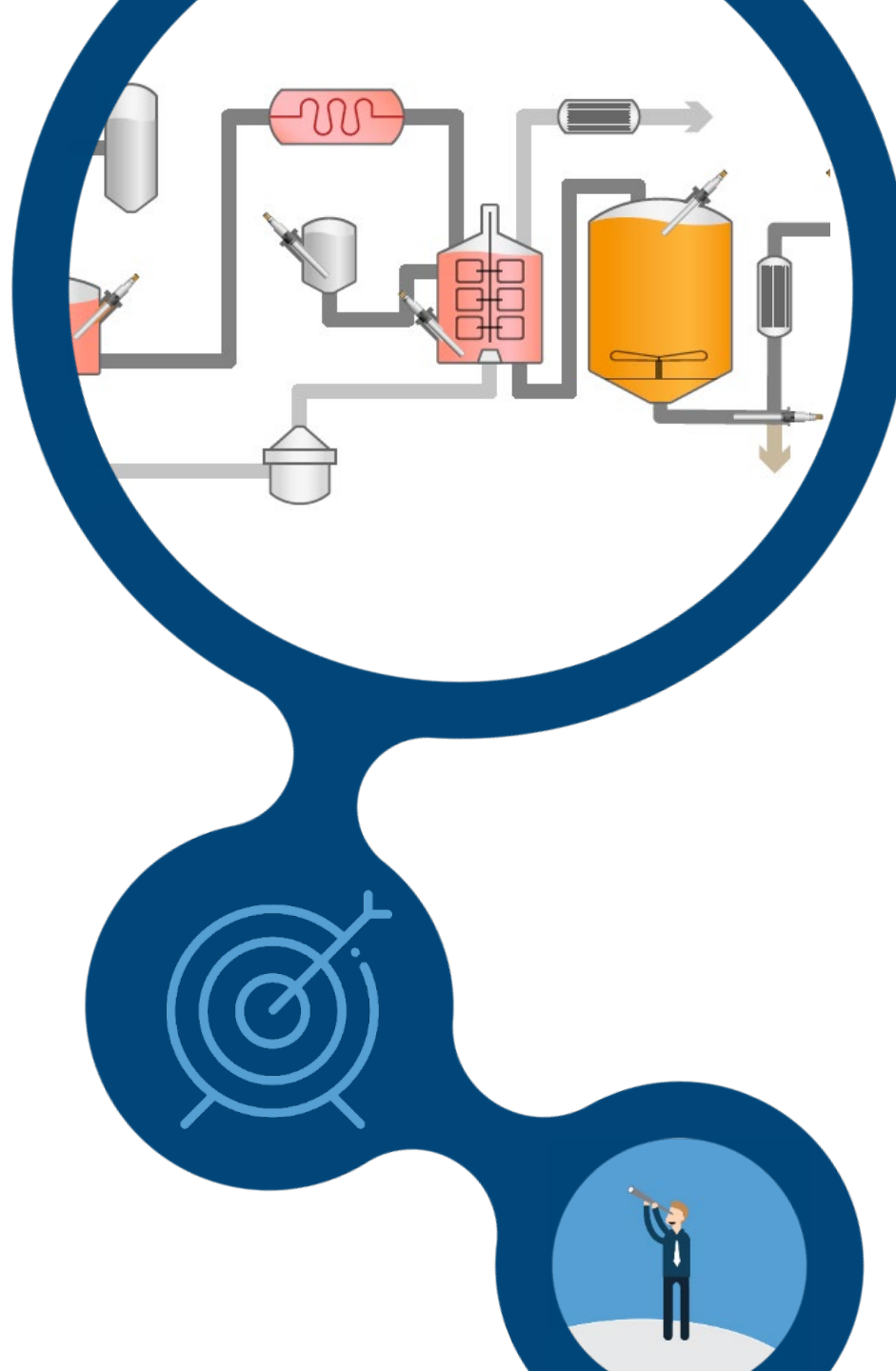


HAMILTON®
THE MEASURE OF EXCELLENCE®



Market Focus

Hamilton has a unique focus on Bioprocesses. Our offering and future innovation are strongly aligned to address the needs of Biopharmaceutical customers.



Customized Solutions

Sensors for ISS



Arc Intelligent Sensors

Wireless adapter

Microtransmitter

pH-sensor



ArcAir software for PC and mobile devices



Arc sensors Advantages

Integrated Micro-Transmitter



30.10.2018 Improved signal and reliability



Troubleshooting & Diagnostic



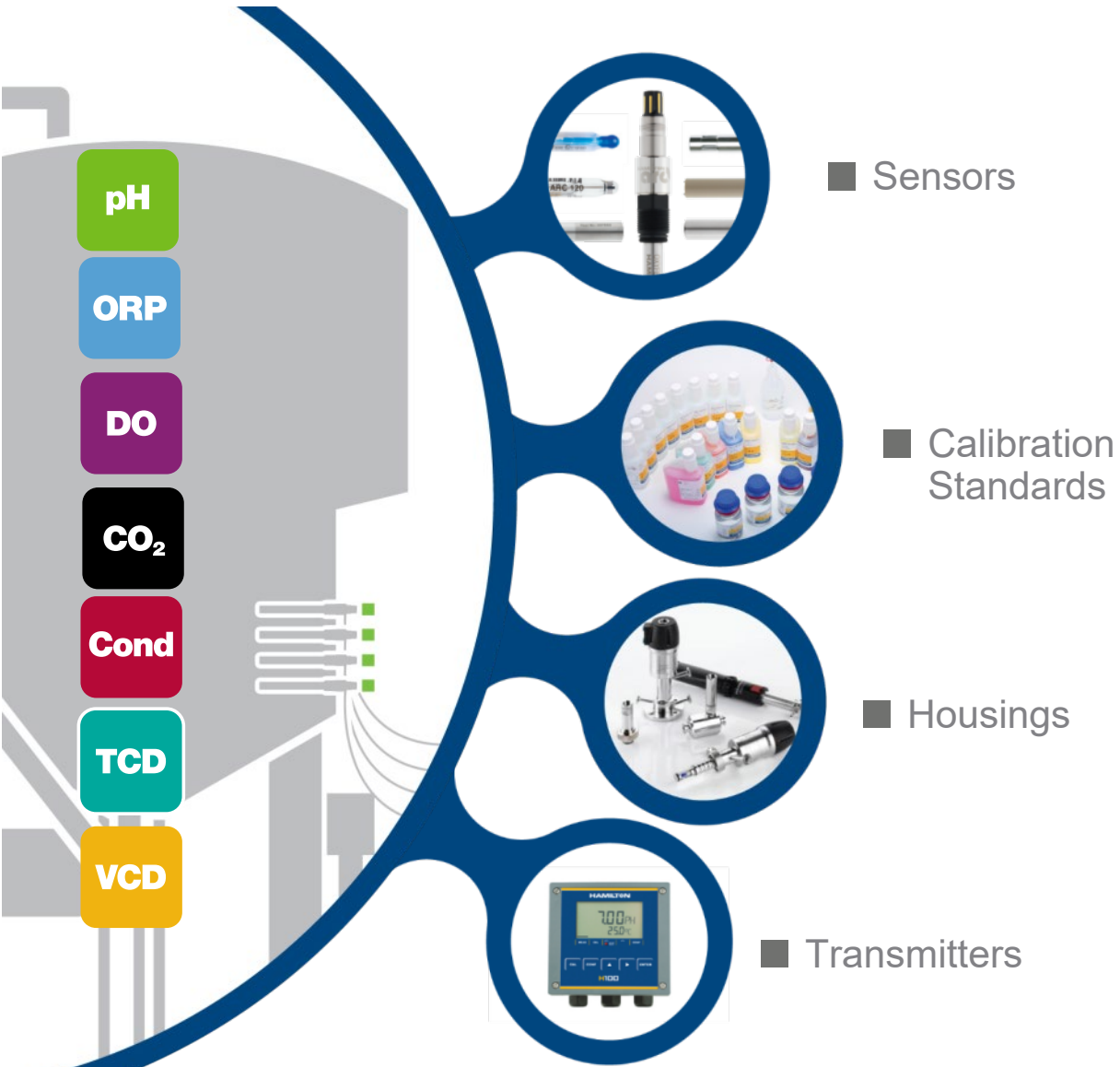
Smaller skid dimensions and Reduce costs



GMP compliance

HAMILTON

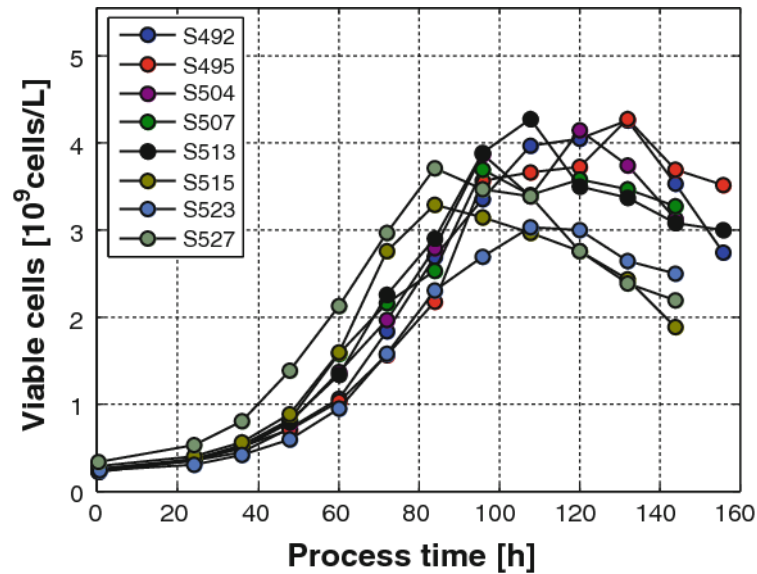
Our Offering



■ ArcAir

Repeatability

the biggest headache for Biopharma Production



To reduce the variability (and improve the yield) it is needed to improve process understanding

Critical Process Parameters (CPP)



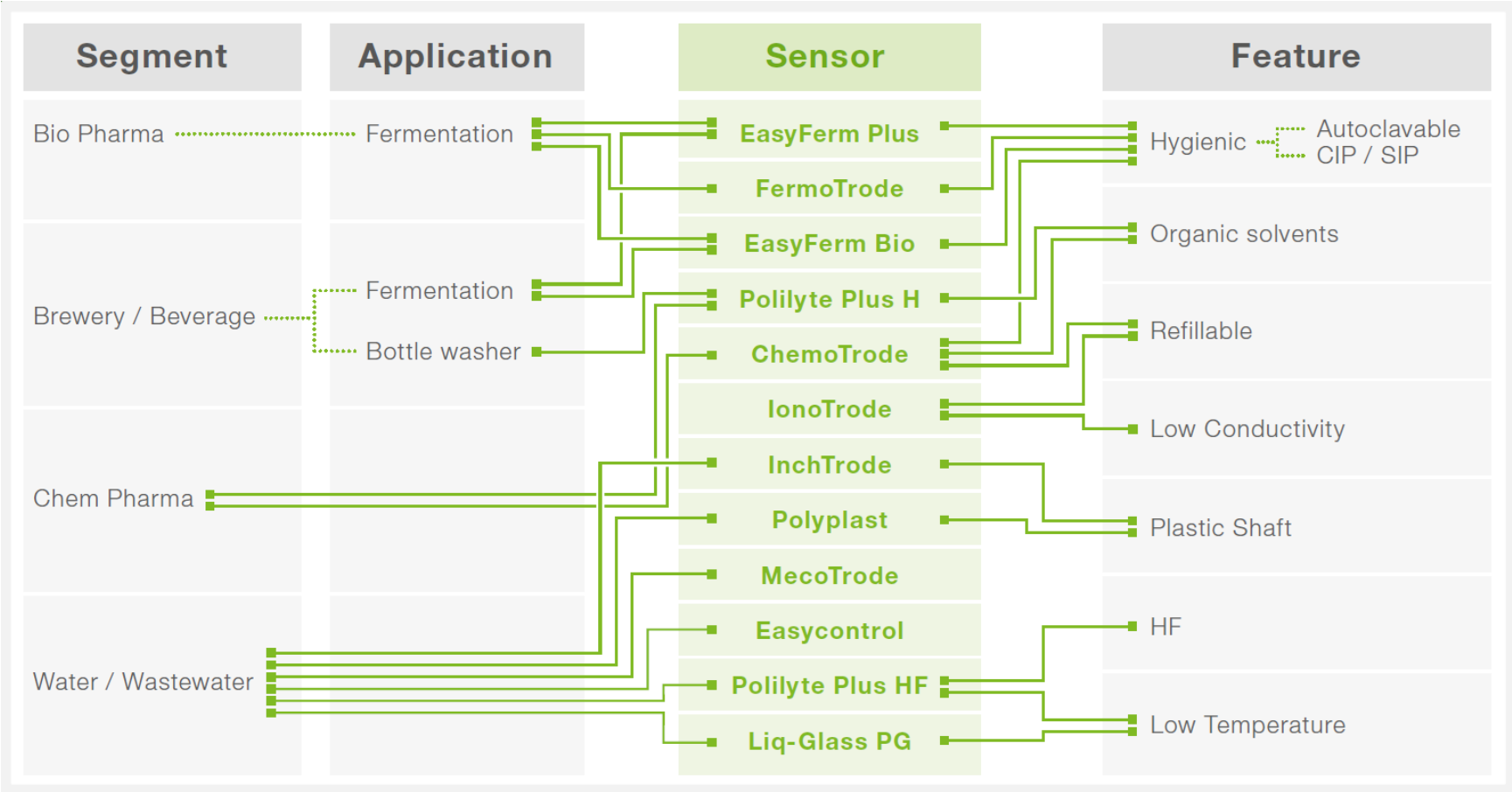
Key Performance Indicators (KPI)





pH and ORP sensors

Applications Overview



pH: EasyFerm Plus / Bio

FDA

USP Class VI

Ex

Ex

Ex

Ex

S8

K8

MS (Memosens)

VP 6

Arc



CERTIFIED

ehedc

TYPE EL - CLASS I

USP<87>
ISO 10993-5

EasyFerm Plus Family Structure						
238633		Code pH glass				
Specifications Measuring range 0 – 14 pH Process temperature 0 – 140 °C (Arc: analog 0 – 110 °C, digital 0 – 140 °C) Pressure range (relative to ambient) 0 – 6 bar Hygienic aspects Autoclavable, SIP, CIP pH glass HB, PHI Electrolyte Phermlyte ← Reference system Everef-F Diaphragm HP Coatramic O-ring EPDM*						
		↓	↓	↓	3	none (S8, K8) or given (Memosens, Arc)
238633 –						← Order Code

EasyFerm Bio Family Structure						
243632						
	Code		pH glass			
Specifications Measuring range0 – 14 pH Process temperature0 – 140 °C (Arc: analog 0 – 110 °C, digital 0 – 140 °C) Pressure range (relative to ambient)0 – 6 bar Hygienic aspectsAutoclavable, SIP, CIP pH glassHB, PHI ElectrolyteFoodlyte Reference systemEveref-F DiaphragmHP Coatramic O-ringEPDM*						
	↓	↓	↓	3	none (S8, K8) or given (Memosens, Arc)	
243632 –					← Order Code	

Duracal

pH Buffer Solutions

Buffer Solutions you can trust

- Highest buffer stability up to 5 years
- Unique reliability with closed loop traceability
 - Traceable to 2 international standards (NIST & PTB)
 - Certified by DAkkS*
- Highest accuracy: up to ± 0.01 pH
- Convenient bottle (250 or 500 mL) with calibration compartment
 - You always have fresh buffer
 - only uses ~15 ml buffer per calibration.
- Certificates available on:

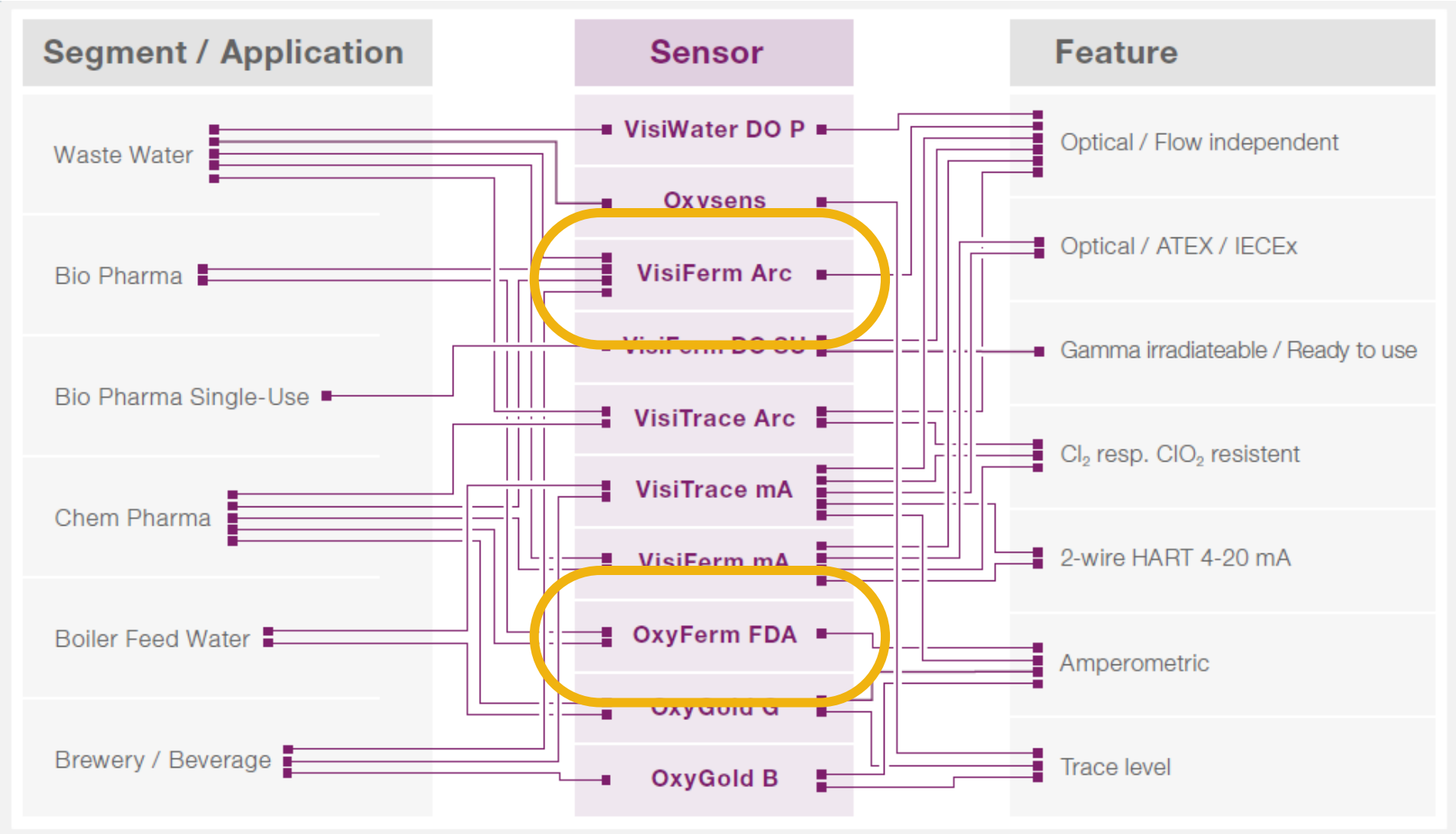
<http://www.hamiltoncompany.com/support/process-analytics/certificates>





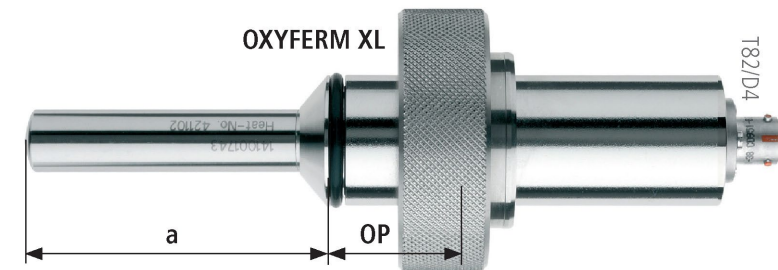
Dissolve oxygen sensors

Applications Overview



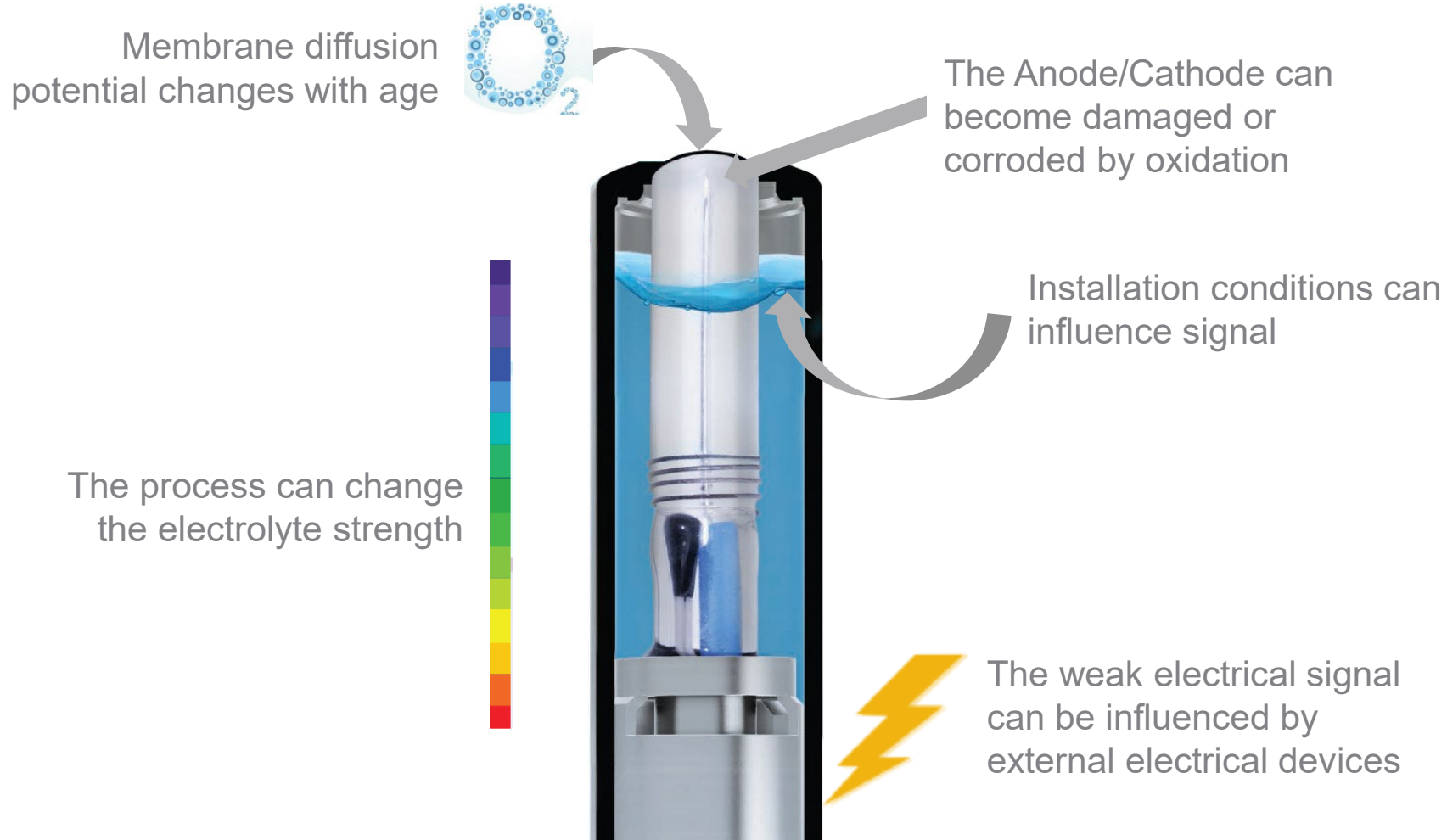
Amperometric Dissolve Oxygen Sensors

OxyFerm



Amperometric Dissolve Oxygen Sensors

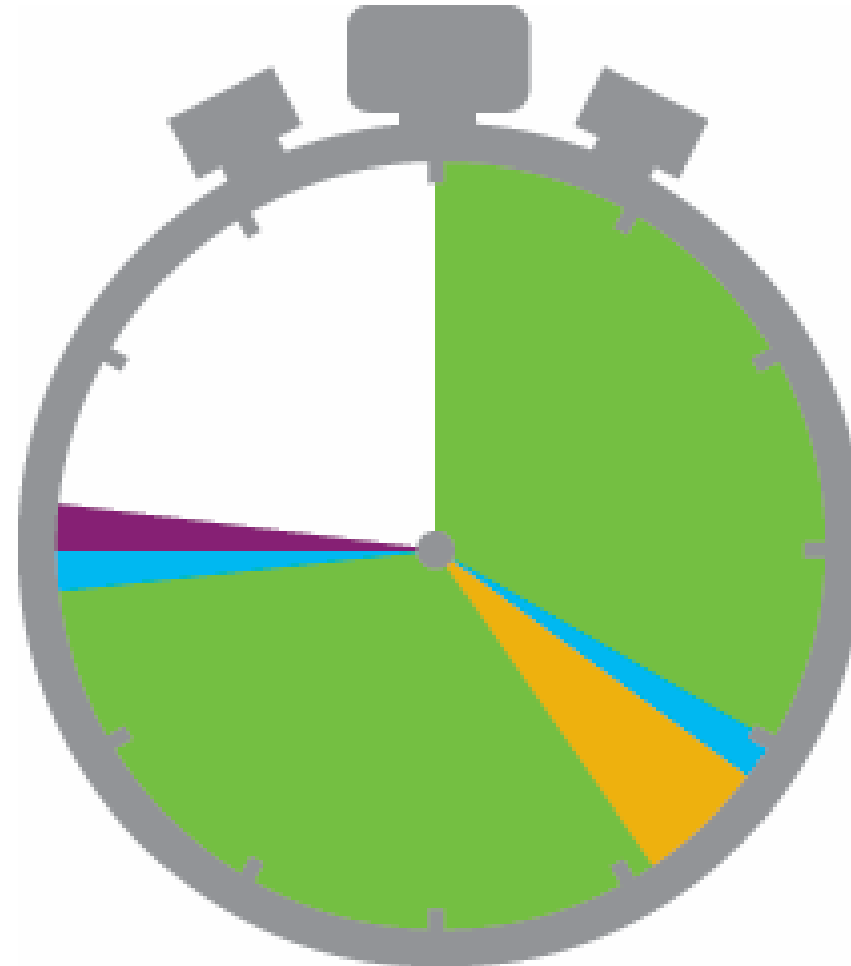
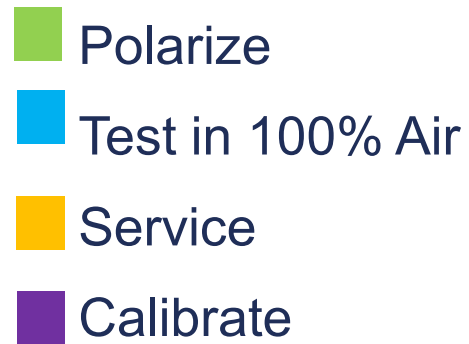
A Fragile DO Measurement System



Amperometric Sensors maintenance

Troubleshooting is Time Consuming

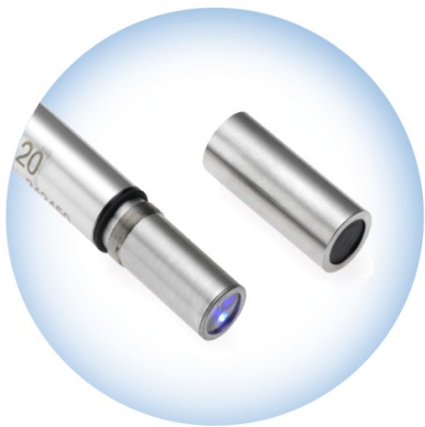
Typical Troubleshooting Time 3-8 Hours



Optical sensor maintenance

Save Time for Troubleshooting and Maintenance

- Warm up
- Service
- Calibrate



Optical Sensors advantages



Inverted
Installations



Fast Response
Time



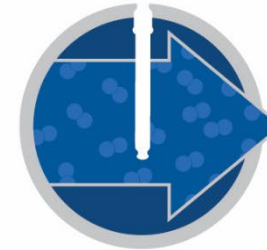
Resistance
Pressure Spikes



No
Signal
Noises



No
 H_2S and
 CO_2
Fouling

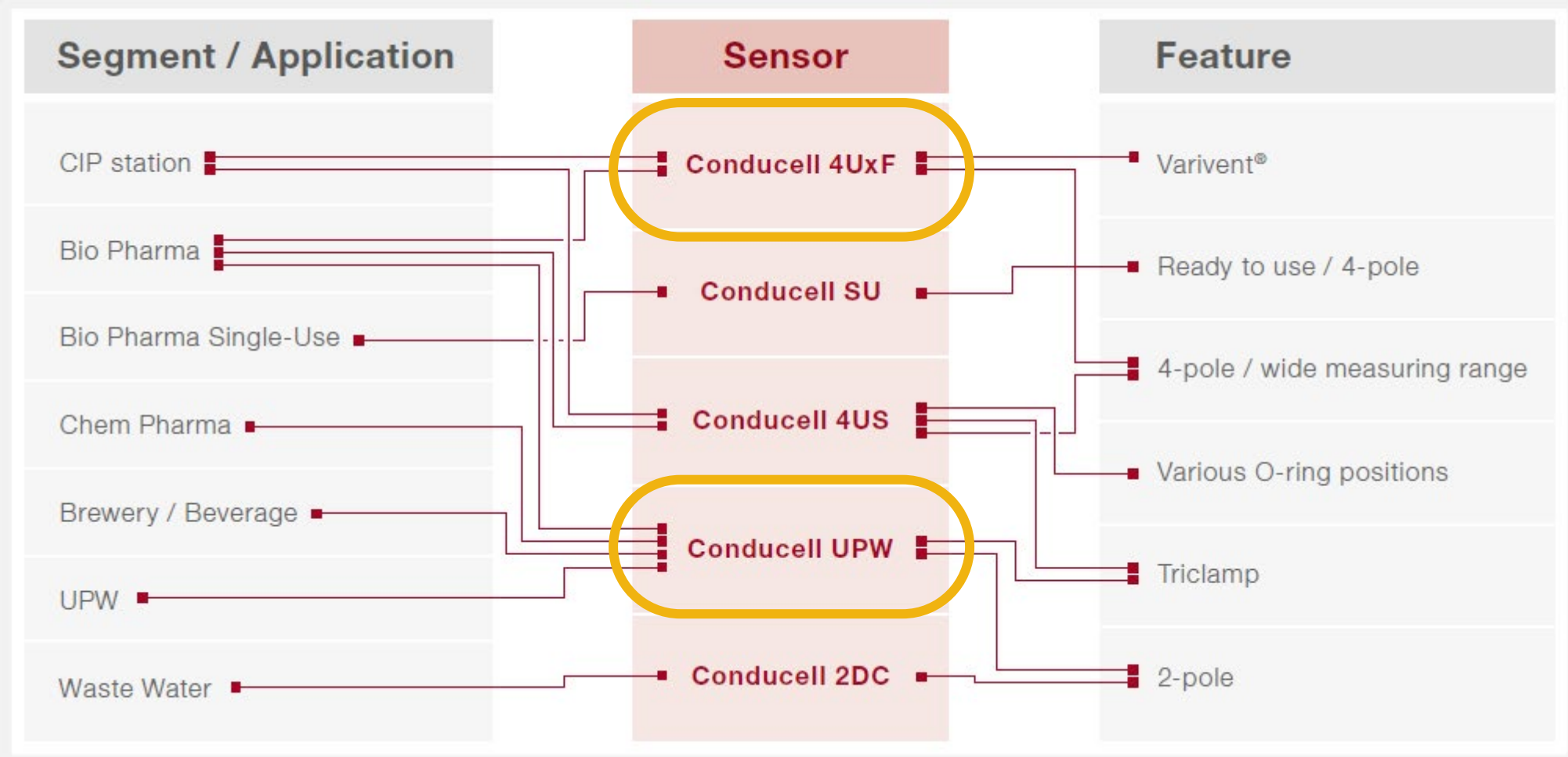


No Flow
required



Conductivity sensors

Application Overview



Conducell 4UxF



Conducell 4USF-VV

Conducell 4UxF Family Structure				
243590	Code		Electrode Material	
	1		Stainless Steel 1.4435	
	2		Platinum (not for Triclamp)	
	3		Stainless Steel 2.4602	
	4		Titanium (not for Triclamp)	
	Code		Electrical Connector	
	1		Arc	
	2		VP 🚫	
	Code		a-length (mm)	
	1		120 (PG13,5)	
	2		225 (PG13,5)	
	3		325 (PG13,5)	
	4		425 (PG13,5)	
	5		30 (PG13,5)	
	6		60 (PG13,5)	
	7		21 – Triclamp 1.5"	
	Code		O-ring Material	
	1		EPDM	
243590 –				← Order Code

Conducell UPW



Conducell UPW Arc

- Measurement of low conductivity directed at Pharmaceutical waters
- Typical applications: USP 645 for WFI, Pure Water
- Hygienic design, FDA Approved
- Surface Finish $R_a < 0.4 \mu\text{m}$ (N5) (16 micro-inches)

Calibration standards



- Remains stable for a minimum of 1 year for the 1.3 µS and up to 3 years for all other values
- Certificate with calibration document from DFM included (also available at www.Hamiltoncompany.com)
- Lot number and expiration date on every bottle
- Bottles are permitted to stay open for a total of 60 minutes

	Value at 25°C	Accuracy	Stability (in months)	Certificate From	Packaging Unit	Volume	Ref
unique	1.3 µS/cm	±1%	12	DFM ¹	Glass bottle	300 mL	238973
	5 µS/cm	±1%	36	DFM	Glass bottle	300 mL	238926
	15 µS/cm	±1%	36	DFM	Glass bottle	300 mL	238927
	84 µS/cm	±1%	18	DFM	Calpack bottle	500 mL	238984
	100 µS/cm	±1%	36	DFM	Glass bottle	300 mL	238934
	147 µS/cm	±1%	18	DFM	Calpack bottle	500 mL	238985
	706 µS/cm	±2%	36	Hamilton	Glass bottle	300 mL	238929
	1413 µS/cm	±1%	36	DFM	Glass bottle	300 mL	238928
	1413 µS/cm	±1%	18	DFM	Calpack bottle	500 mL	238986
	12880 µS/cm	±1%	18	DFM	Calpack bottle	500 mL	238988
	100 mS/cm	±1%	36	Hamilton	Glass bottle	300 mL	238935

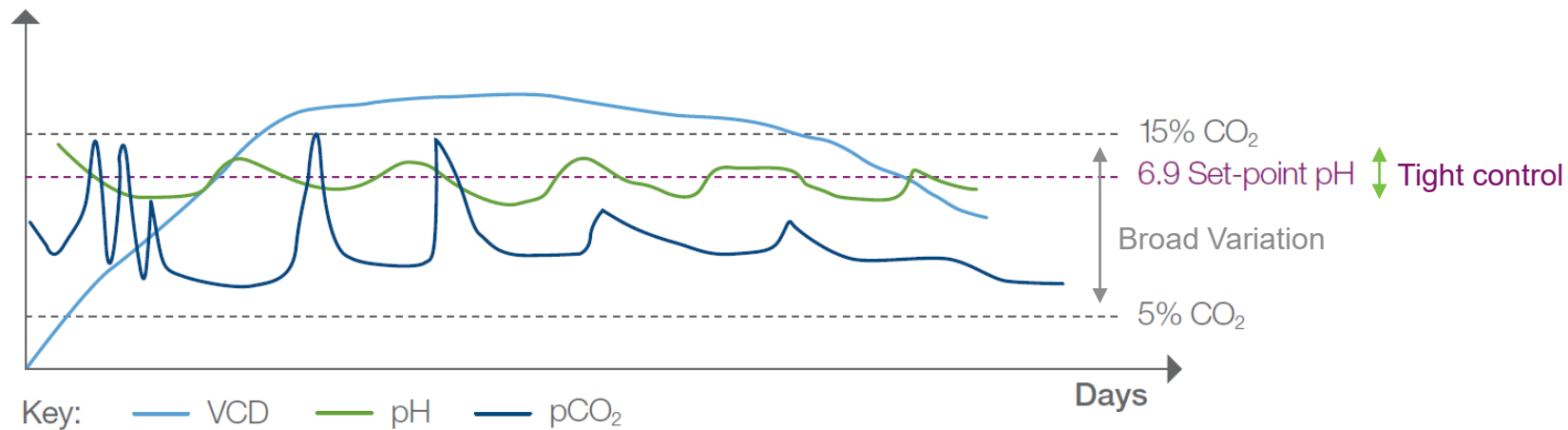


Dissolve CO2 sensor

Is CO₂ Under Control?

pH Tight Control $\neq$ DCO₂ Tight Control – Even in Cell Culture

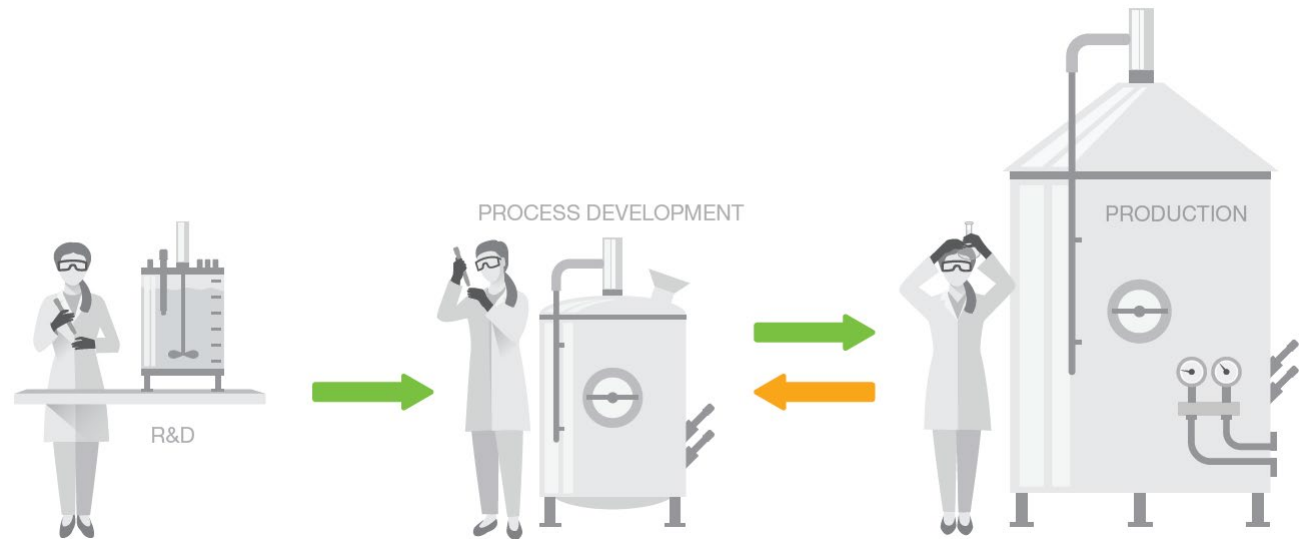
- CO₂ often assumed to be under control when pH is under control
- CO₂ can spike above optimal without pH excursions as this is compensated by quick base addition



Bioreactor Size Impacts CO2

Different Dissolution and Stripping Across Scales

- Without dissolved CO2 control a process optimized in R&D could behave differently in PD or Production
- Establishment of a golden profile can streamline scale-up
- Controlled CO2 ensures that benefits found in R&D are retained in production



Optical Dissolve CO2 sensor

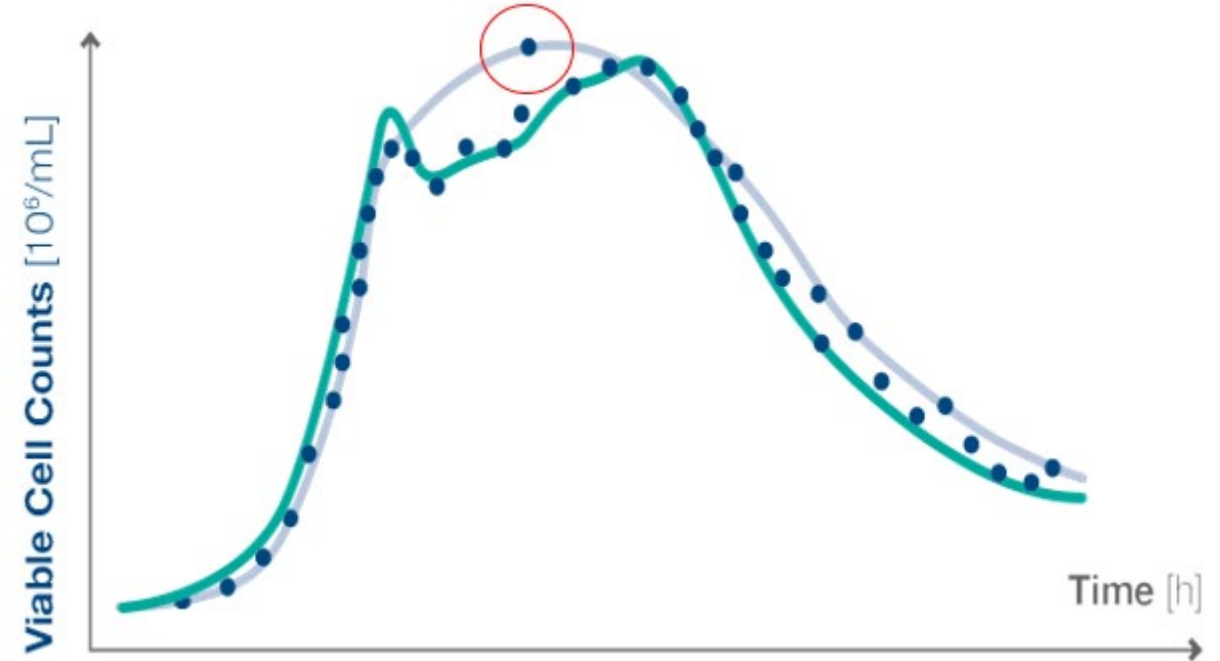




Cell Density sensors

Offline Sampling

Time Consuming

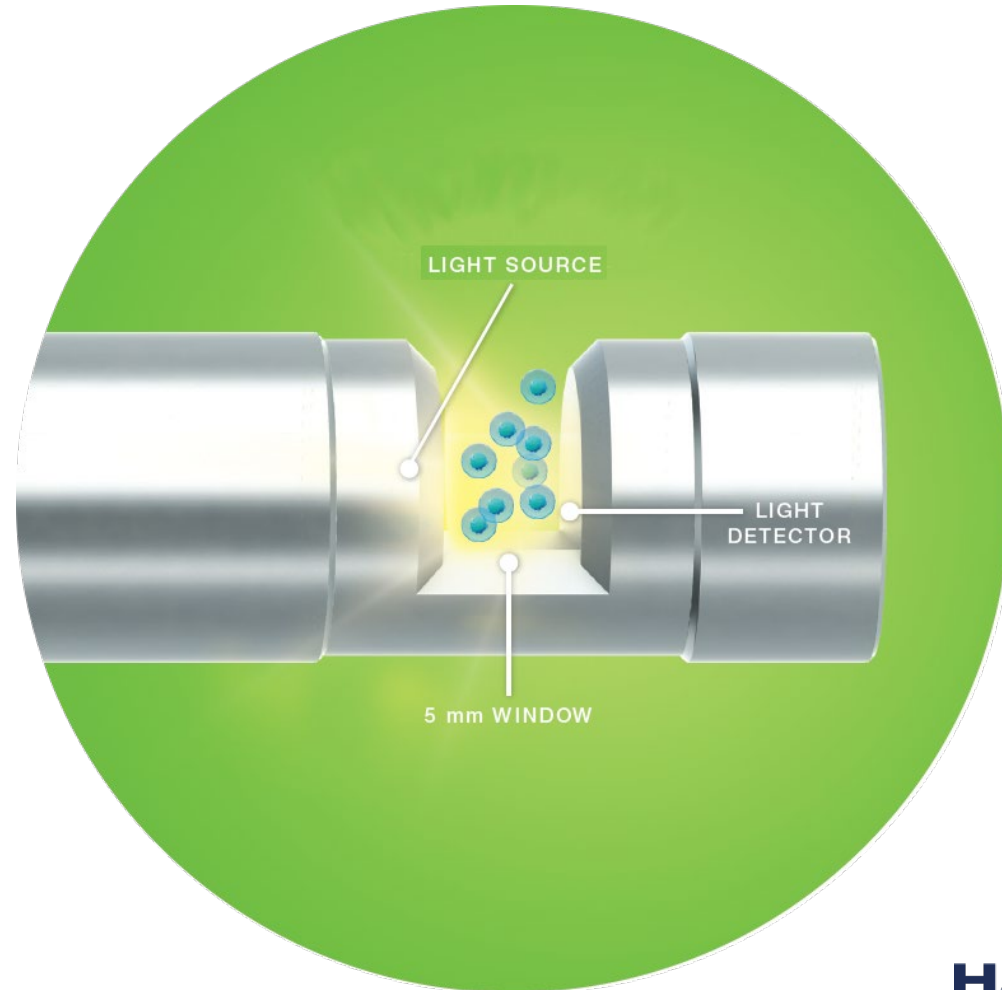


- Events may be missed
- Only a reactionary window into the past
- Errors may occur

Dencytee – Total Cell Density

Monitoring of the Optical Density

- Measurement at NIR – no influence of medium color
- Simple measurement of cell growth
- Reliable values during growth phase
- Early detection of process deviations



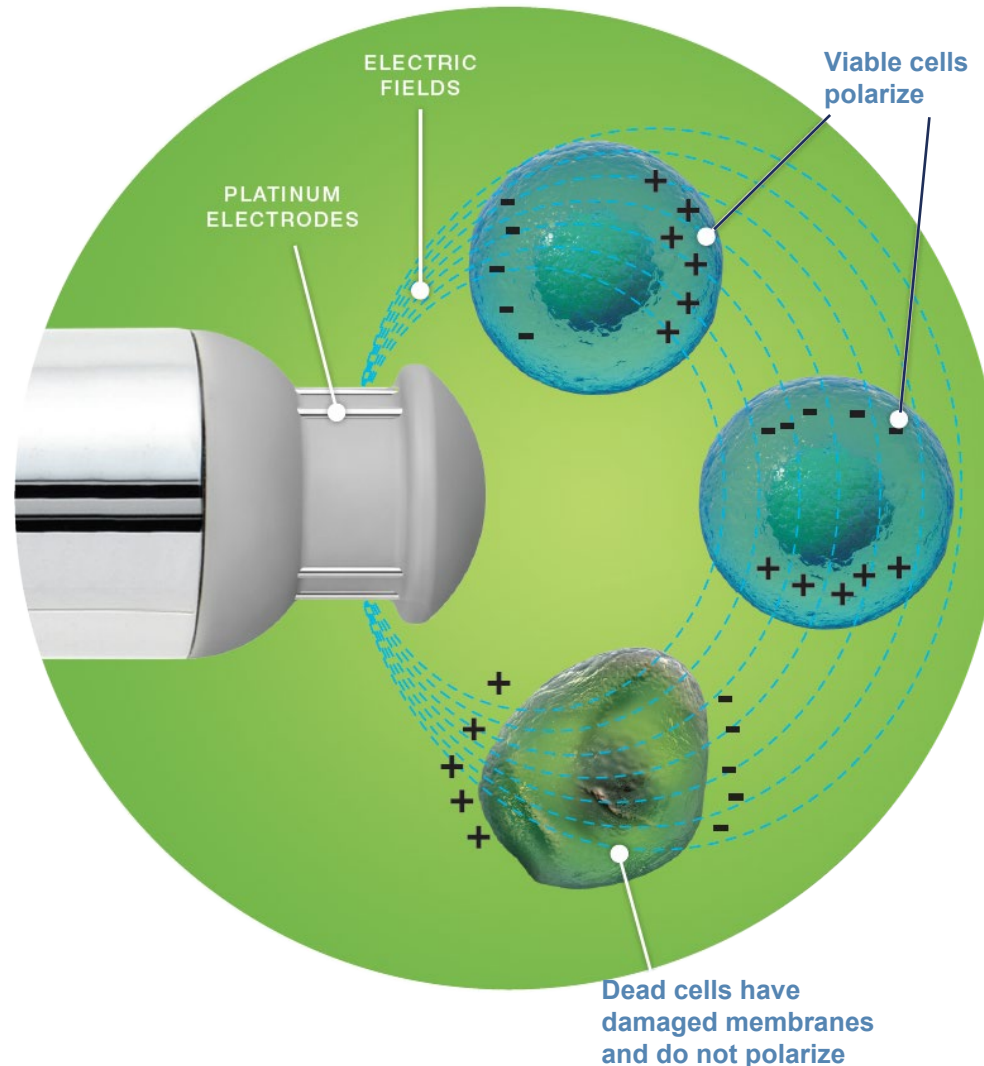
Dencytee Arc



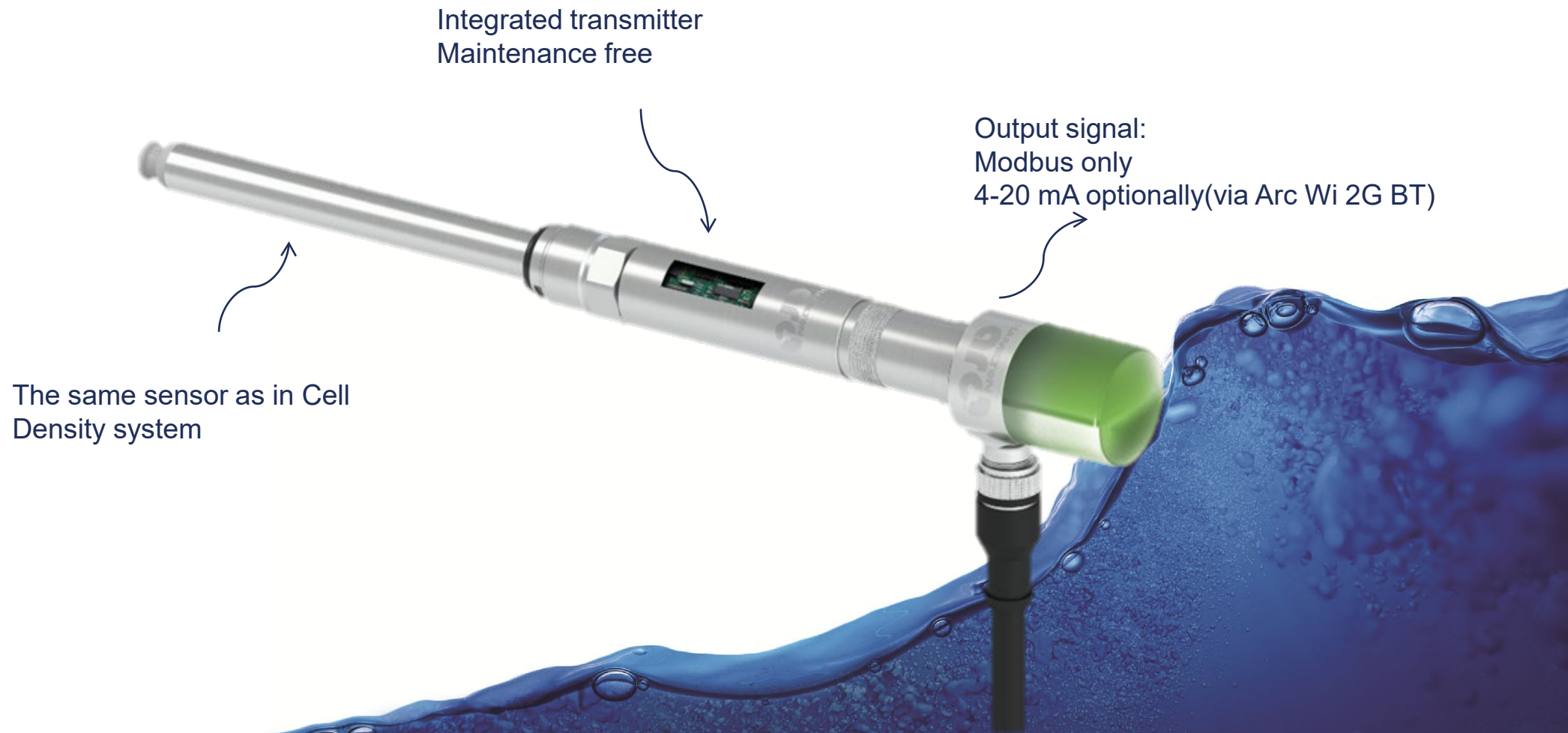
Incyte – Viable Cell Density

Monitoring of Permittivity

- Permittivity correlates linear to viable cell density
- No influence of media, microcarrier, dead cells, or cellular debris
- Detection of changes in cell physiology
- Precise control of viable cell density over the complete process



Incyte Arc



How to sell our sensors?



pH



ORP



DO



VCD



TCD



CO₂



Cond



Cond

- Used widely
- Relatively cheap
- Short sales cycle 1-3 month
- Relatively short life cycle 3-12 month
- Easy to retrofit a competitor solution

- Useful in specific applications
- Tech and Application specialist
- Tests
- Visits
- Relatively expensive
- Sales cycle 6-18 month
- Life cycle >12 month



Check

- Sensor type
- Its length
- Connection type
- Picture of it
- Contact to Hamilton



Contact to Hamilton



Awaiting for your requests!