

R&D systems™
by biotechne

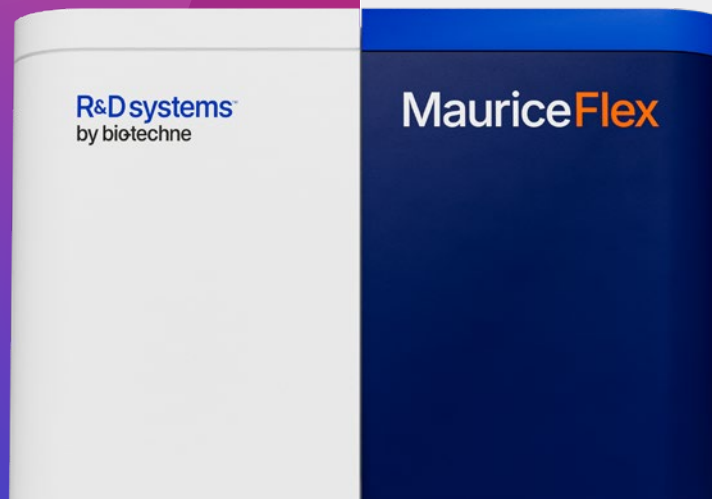
iCE3 to Maurice *Transition Support*

Same Technology, Same Results, **More Benefits**



Same Technology, Same Results, More Benefits.

We understand that the iCE3 to Maurice transition is a major commitment for your organization. This is why we offered full iCE3 service support and consumables for >7 years after we announced the iCE3 system's discontinuation in December 2021 (effective June 30, 2022). We are providing this extended timeline until June 30, 2029 because of the considerable number of commercial products with iCE assays (~300) and the numerous additional BLAs in development or are currently being reviewed by regulatory agencies. In addition, our next generation Maurice and MauriceFlex platforms offer the same high-quality results as the iCE3 systems plus more capabilities for your lab.



iCE3 to Maurice Bridging Studies and Results

There are several peer reviewed publications that show that iCE3 and Maurice system data are comparable.

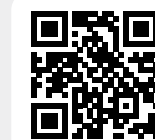
In the first study involving 20 labs globally¹ Madren et al (Biogen) showed that both the iCE3 and the Maurice systems can perform icIEF in a robust manner to monitor charge heterogeneity of monoclonal antibodies and fusion proteins. The electropherograms for both the NISTmAb and the rhPD-L1-Fc are consistent across all laboratories and between both the iCE3 and the Maurice instruments. The iCE3 and Maurice instruments produce identical apparent pI values for the main isoform and comparable relative peak areas for the acidic, main, and basic isoforms for the NISTmAb. Both instruments also produce comparable quantitative results for rhPD-L1-Fc. The 20 labs participating in the study were based in the US, Europe and China and consisted of 17 biopharma companies, 1 Immunodiagnostic company and the NIFDC.

In a recent study, a team at Boehringer Ingelheim designed an instrument comparability study in QC to understand potential performance differences between instruments to rationalize risk assessment

and decision process. Their study confirmed "equal or better performance of the iCE3 to Maurice systems in all parameters and serves as a basis for seamless continuation of release measurements on Maurice C".

In addition, customers from other Pharma and Biotech organizations have also presented their bridging study results in posters and talks at scientific conferences and User Meetings showing the comparability of their iCE3 and Maurice data (Table 1). These studies range from a single company to a global study with 20 sites and the bridging studies have varied from being program specific to having a statistical approach including a variety of molecules like ADCs, fusion proteins, monoclonal antibodies, and more.

The results have shown comparable results for 99+% of the tested molecules. For the few misses, the companies have concluded that their iCE3 assays were not optimized. An optimized iCE3 method is critical for a successful method transfer to the Maurice system.



Explore Resources

Scan the QR code or visit
rndsistemas.com/ice3tomaurice

FIGURE 1
Compare Workflows

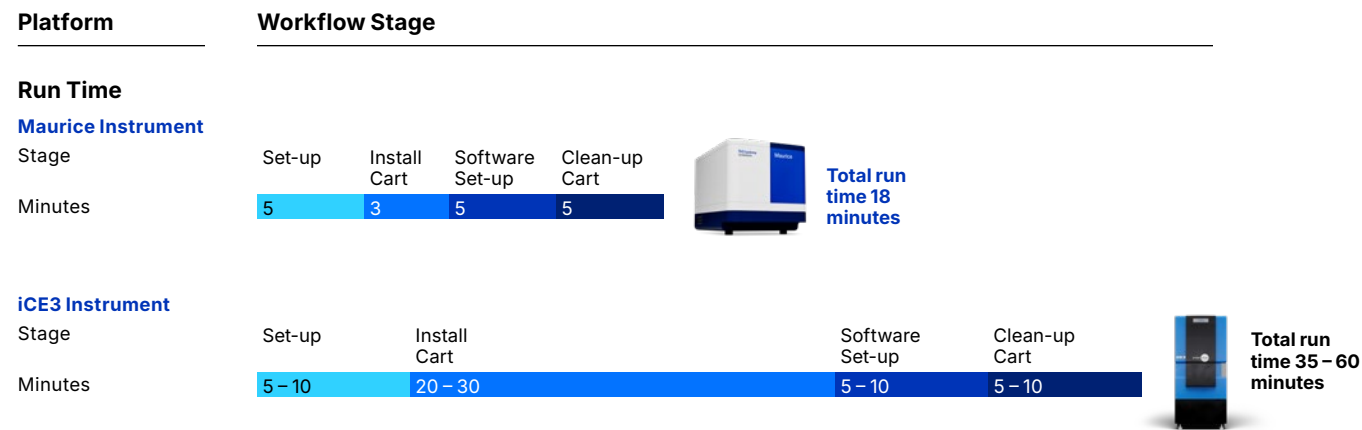


TABLE 1
Compare Models

	ICE3	Maurice	MauriceFlex	Maurice C.
icIEF Charge Application	✓	✓	✓	✓
CE-SDS Size Application		✓	✓	–
icIEF Fractionation		–	✓	–
Onboard Mixing for Sample Prep	✓ (Only with the Alcott autosampler)	✓		✓
Absorbance Detection	✓	✓	✓	✓
Native Fluorescence Detection (4X Sensitivity)		✓	✓	✓
Integrated Autosampler	✓			
Software	Compass for ICE	Compass for ICE, Empower CDS, Chromeleon CDS	Compass for ICE, Empower CDS	Compass for ICE, Empower CDS, Chromeleon CDS



Xiaoping He
Sr. Principal Scientist,
Pfizer (retired)



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From Your Peers: The Benefits of Transitioning from iCE3 to Maurice Instruments

What are some of the key advantages of the Maurice and MauriceFlex instruments compared to the iCE3 system?

Maurice:

- Very intuitive and easy setup both hardware and software, extremely user friendly for running assay and system maintenance
- Direct data acquisition bridges the compliance gap of data integrity
- Native fluorescence features increased detection sensitivity 3-20 folds, making it possible for low abundance sample analysis
- No new method development necessary for existing iCE3 users, simply adopt the iCE3 method onto Maurice when using UV 280 detection
- Capability of icIEF charge and CE-SDS size analyses with one instrument

MauriceFlex:

- Does everything Maurice can, as listed above
- Allows fraction collection of separated charge species for subsequent analysis including MS characterization for intact protein structural identification, peptide mapping for more detailed study on post-translational modification (PTM) analysis, and potentially potency assay for degraded charge species of stability samples to gain insight on charge-related CQAs.

Is there any specific advice or resources you would recommend to other iCE3 Users who are transitioning to Maurice?

- Do custom appropriated bridging study using representative iCE methods on iCE3 and Maurice instruments
 - prepare a set of samples representing the customer’s portfolio
 - include multiple analysts of various levels of iCE experience, if possible
 - involve DoE design to simplify experiment execution and data analysis integrity and validity
- If any significant discrepancy between iCE3 and Maurice occurs in a well-designed and executed bridging study, investigate the iCE test method to make sure that the separation conditions are optimal, e.g., sample prep composition of ampholyte range, strength, brands, detergent or other additive usage, focus time, etc.
- Some particularly valuable resources I would like to recommend
 - Bio-Techne website and tech support
 - CASSS CE Pharm conference
 - Peers in the Pharma industry
 - iCE3 and Maurice equivalency evaluation reports and presentations from Pfizer and Janssen, which might be accessed via Bio-Techne Tech Seminars at CE Pharm 2024, WCBP 2025, and CE Pharm 2025.

TABLE 2

Additional bridging studies presented during poster sessions and technical talks

Event	Date	Bridging Studies Summary
Festival of Biologics	November 2021	In a technical talk, Minna Mattila from Medix Biochemica presented the initial results from the 20-lab global assessment prior to publication, ¹ highlighting the strong and consistent correlation between the iCE3 and Maurice systems for charge heterogeneity analysis of the NISTmAb and the rhPD-L1-Fc fusion protein.
European User Meeting	October 2022	In a poster, a scientist from Lonza AG, ³ the icIEF method using the Maurice instrument passed all the acceptance criteria set in the development plan. This method was determined to be fit for purpose in charge variant analysis for process development samples; Maurice would replace iCE3 systems, allowing for fast and high-quality analysis without compromising the timelines.
Scientific Conference	2022	In a technical talk, a scientist from a multinational CDMO presented the results from a bridging study that analyzed 5 different mAbs on the iCE3 and Maurice systems and demonstrated that the data was not only comparable between the two instruments, but that the Maurice instrument improved productivity with shorter run times, operator training times, and fewer errors.
Scientific Conference	2023	In a technical talk, a scientist from a major Pharma company presented the results from a bridging study that evaluated 13 late stage and commercial products with one mAb not reproducing iCE3 results with Maurice. Further investigation showed that the iCE3 assay in this case was not optimized so the discrepancy was later addressed by modifying the assay.
Scientific Conference // User Meeting	2024	In a technical talk at two separate events, a scientist from a second major Pharma company presented the results from a bridging study that demonstrated that the method performance is equivalent between the iCE3 and Maurice systems based on precision, system suitability, and reportable results. Furthermore, the results of the study allow for interchangeability of instruments. The speaker also described their implementation status following the bridging study: 1) for new molecules, methods are developed on iCE3 and Maurice platforms; 2) for existing molecules (pre-Maurice), comparative testing is conducted on both instruments; and 3) for late phase molecules, co-validation is implemented on both iCE3 and Maurice systems.
Scientific Conference // User Meeting	2025	In a technical talk at two separate events, a scientist from a third major Pharma company presented the results from a bridging study that evaluated 18 biomolecules, demonstrating method agreement between the iCE3 and Maurice instruments for charge heterogeneity determination of these various biotherapeutic modality products. Each of the four reportable values (% Acidic, %Main, %Basic and Main peak pI) demonstrated an R2 >= 0.99) between the systems. Based on these results, it was concluded that iCE3 and Maurice instruments are equivalent for iCE-based charge heterogeneity analysis.

In summary, these numerous bridging studies, as well as discussions with many users who have or are making the transition from iCE3 to Maurice systems have helped us to develop some guidelines and recommendations for Bridging Study Models (Table 3).

TABLE 3

iCE3/Maurice Bridging Study Model Options

Parameter	① Molecule Specific	② Statistical	③ Stressed mAb	④ Develop/validate assays on both iCE3 & Maurice
# of Molecules	1 to 15	15 plus	1 or more	*
# of Maurice	2	3	1 or more	*
# of iCE3	1	3	1 or more	*
# of Analysts	3	4	1 or more	*
# of Days	3	3	3	*
# of Cartridges – iCE3	Up to 3	Up to 9	3 or more	*
# of Cartridges – Maurice	Up to 6	Up to 9	3 or more	*
Allowable Variability	+/- 3%	Statistical	SD: 5–10% NSD: 15%	*

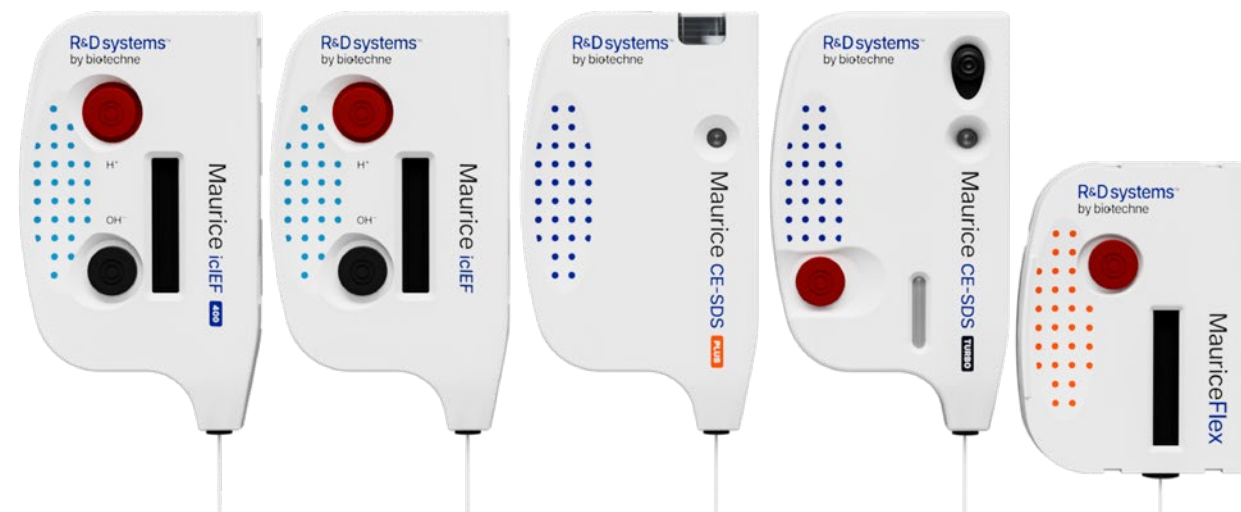
*Parameters may vary by company. A bridging study may not be required.

Other Options

- ⑤ Do not specify instrument name or model
- ⑥ Combine Options

Regulatory Approach

Submit addendum or notification to existing filing(s)

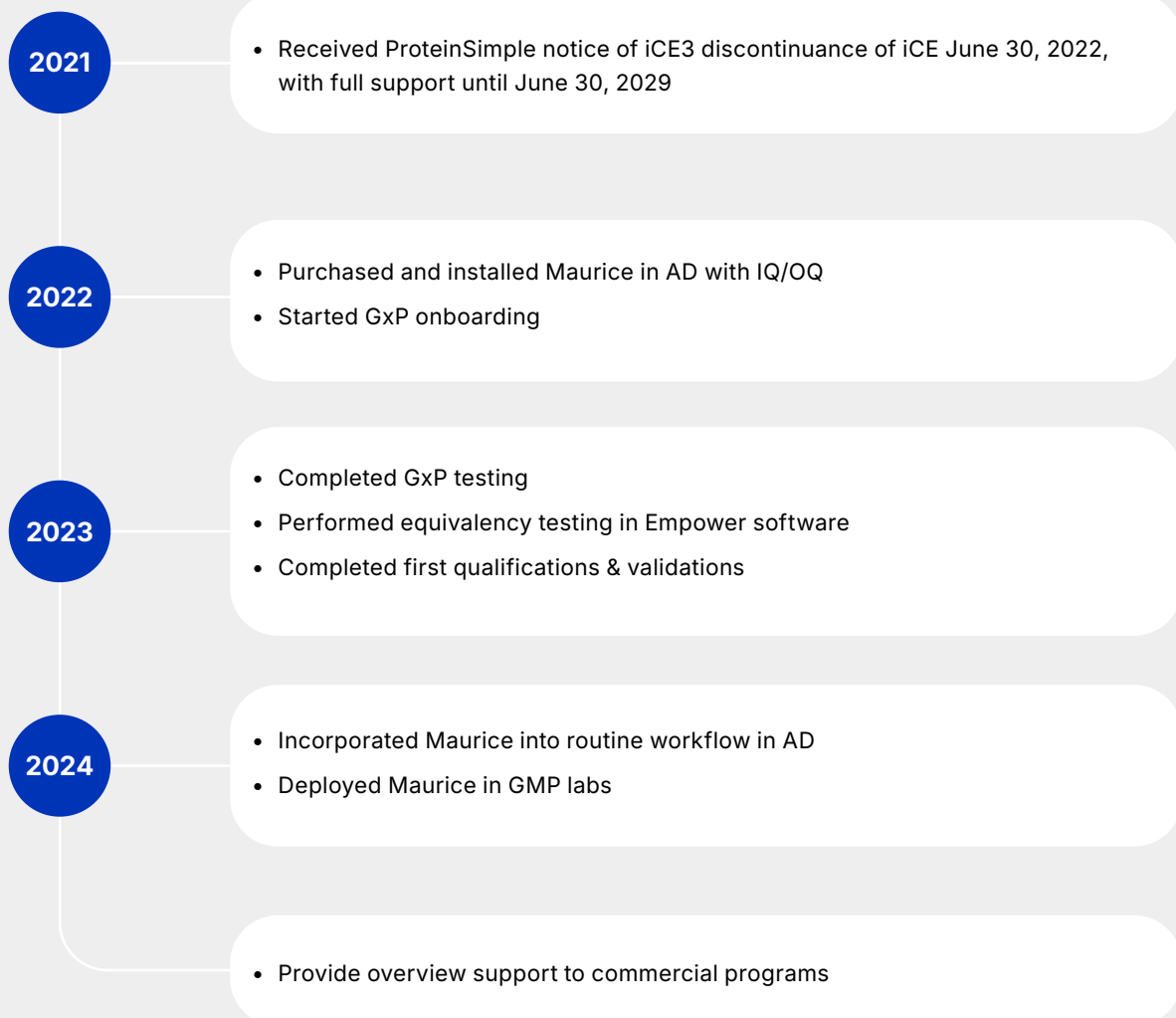


Where are Companies in Their Transition to Maurice?

Some have completed bridging studies and have converted to Maurice in earlier stages including Process Development and Analytical Development. They are now developing their regulatory strategy for Commercial Products including bridging study designs. Others may be faster or slower in the process. See an example of a user's transition timeline to Maurice (Table 4).

TABLE 4

Example timeline of an iCE3 to Maurice System transition



Frequently Asked Questions

Q1: We have invested significantly in iCE technology at multiple sites and in different countries. How can you help us financially?

A1: Bio-Techne has designed a special iCE3 Trade-in program for our accounts. Simply estimate the number of trade-ins for the next year and receive significant trade-in credits toward Maurice or MauriceFlex purchases.

1. Annual trade-ins are cumulative year-to-year, so you multiply your savings
2. Trade in an iCE3 system from one site and receive a trade-in credit at another site for any Maurice instrument
3. Trade in other qualifying instruments in your lab, including PA800plus, GXII, Bioanalyzer, HPLC and others (please inquire) and receive a trade-in value similar to an iCE3 system

Q2: We want to trade in an iCE3 system now but can't lose its testing capacity for 4 to 7 months while we validate the Maurice instrument.

A2: You can continue to use your iCE instrument trade-in for up to 12 months to maintain your testing capacity until the Maurice is validated.

Q3: We are seeing some inconsistencies in the iCE and Maurice data. How can we get help?

A3: For more information and assistance, please contact us in North America at support@proteinsimple.com and in Europe, at instrument.support.emea@bio-techne.com.

Q4: We use iCE3 pl markers in some of our Maurice assays. Can we purchase these and other iCE3 reagents after June 30, 2029?

A4: Yes, we will continue to sell any common iCE3/Maurice reagents indefinitely (Table 5).



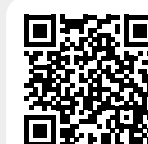
TABLE 5

iCE3/Maurice Reagents and Consumables that will be available after June 30, 2029

Product Code	Product Name	Product Description
102505	0.5% Methyl Cellulose Solution	0.5% Methyl Cellulose Solution, 100 mL Use for the wash cycle between injections; 2 bottles/pack
101876	1% Methyl Cellulose Solution	1% Methyl Cellulose Solution, 100 mL used for sample preparation.
101996	iCE280/iCE3 pI Marker 9.50	pI Marker 9.50, 200 µL
102018	iCE280/iCE3 pI Marker 3.21.	pI Marker 3.21, 200 µL
102093	ICE System Suitability Kit	Use to run a control test on 10 separate occasions. The kit contains a standard sample with Hemoglobin AFSC.
102142	Balancing Waste vial, 4 mL. 2/pk.	Balancing vial - 4 mL with level lines. 2/pkg
102170	iCE280/iCE3 pI Marker 7.55	pI Marker 7.55, 200 µL
102171	iCE280/iCE3 pI Marker 7.90	pI Marker 7.90, 200 µL
102219	iCE280/iCE3 pI Marker 9.77	pI Marker 9.77, 200 µL
102220	iCE280/iCE3 pI Marker 6.14	pI Marker 6.14, 200 µL
102221	iCE280/iCE3 pI Marker 2.85	pI Marker 2.85, 200 µL
102222	iCE280/iCE3 pI Marker 3.59	pI Marker 3.59, 200 µL
102223	iCE280/iCE3 pI Marker 4.65	pI Marker 4.65, 200 µL
102224	iCE280/iCE3 pI Marker 5.12	pI Marker 5.12, 200 µL
102225	iCE280/iCE3 pI Marker 5.85	pI Marker 5.85, 200 µL
102226	iCE280/iCE3 pI Marker 7.05	pI Marker 7.05, 200 µL
102227	iCE280/iCE3 pI Marker 7.40	pI Marker 7.40, 200 µL
102229	iCE280/iCE3 pI Marker 8.40	pI Marker 8.40, 200 µL
102230	iCE280/iCE3 pI Marker 8.79	pI Marker 8.79, 200 µL
102231	iCE280/iCE3 pI Marker 9.22	pI Marker 9.22, 200 µL
102232	iCE280/iCE3 pI Marker 10.10	pI Marker 10.10, 200 µL
102233	iCE280/iCE3 pI Marker 10.45	pI Marker 10.45, 200 µL
102349	iCE280/iCE3 pI Marker 9.46	pI Marker 9.46, 200 µL
102350	iCE280/iCE3 pI Marker 4.22	pI Marker 4.22, 200 µL
102407	iCE280/iCE3 pI Marker 7.65	pI Marker 7.65, 200 µL
102408	iCE280/iCE3 pI Marker 8.18	pI Marker 8.18, 200 µL
102409	iCE280/iCE3 pI Marker 6.61	pI Marker 6.61, 200 µL
102506	ICE Electrolyte Kit	Kit contains Anolyte and Catholyte Solutions in 0.1% MC (100 mL each) to fill electrolyte tanks.
042-691	Maurice cIEF 500 mM Arginine	Maurice cIEF 500 mM Arginine, 500 µL. For use as a cathodic blocker.

Resources**Optimizing your iCE3 transition experience**

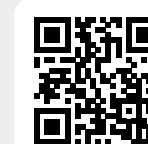
Dr. Tyagi discusses key steps to facilitate the transition. She shares data comparability results from publications, bridging study summaries and models, example timelines, hands on differences between iCE3 and Maurice systems, frequently asked questions (FAQs), and more.

**Watch Video**

Scan the QR code

<https://youtu.be/eQrfWdUK9As>**iCE3 Transition Virtual User Meeting**

This webinar features experts who have been part of successful bridging studies. They share their experience in instrument changes, bridging study designs and results, technical tips, and best practices. Learn about the additional capabilities Maurice Platforms offer.

**Watch Webinar**

Scan the QR code

bio-techne.com/wbr-ice3-um**A successful iCE3 to Maurice transition story**

This blog illustrates a study conducted by Fujifilm for their transition from the iCE3 to Maurice system, involving 5 different mAbs on each instrument and assessing them for reproducibility and data quality.

**Read Article**

Scan the QR code

rndsystems.com/blog-fujifilm**References**

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- Ries et al, Universal Study Design for Instrument Changes in Pharmaceutical Release Analytics. *BioRxiv* 2024.12.11.627881; doi: <https://doi.org/10.1101/2024.12.11.627881>
- Zabala Garcia et al, Moving From ICE3 to Maurice: Maurice Qualification & Implementing icIEF Test Method for mAb Charge Heterogeneity. Scientific Poster (2022); <https://www.rndsystems.com/resources/literature/ionza-ice3-to-maurice-qualification-study>
- Vanessa Tavernier, et al. Capillary isoelectric focusing (icIEF) bridging study between iCE3 and Maurice equipment. Application Note (2022); <https://www.quality-assistance.com/en/resources/webinars-presentations/icief-bridging-study-between-ice3-and-maurice-equipment#>

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