



International Biophysics Corporation

IBC Gas Cell™ and Quick Cell™ Validation Report



Introduction

The purpose of this report is to validate the substitution of IBC Gas Cells™ and Quick Cells™ for the corresponding CDI Gas Cells and Quik Cells for use in the CDI 300 and 400 series monitoring systems. The IBC products are manufactured under U.S. Patent Number 5,641,458. They are listed with the U.S. FDA under section 510(k) and are manufactured under FDA/GMP and ISO 9001 Guidelines. Tens of thousands of these cells have been shipped without a single reported incident, a safety record that excels within the medical device industry. This exceptional quality performance is a direct result of exhaustive testing and development conducted prior to the market release of the products in 1995. The product you are about to use incorporates the same general geometry you have always used, with the identical membrane materials you have come to trust while at the same time incorporating the unique and superior Safe-T-Seal™ design that has been recognized by the U.S. Patent Office.

Test Results

The IBC Gas Cells and Quick Cells were tested for Toxicity following the FDA Tripartite Test protocol and the U.S.P. plastic class 6 Test protocol. All materials used in the IBC products meet or exceed these standards. The product assemblies were tested for hemolysis in a simulated perfusion circuit for 6 hours and found to induce no hemolysis when compared to an identical circuit with no IBC cells in line. The assemblies were tested at 20 p.s.i. (>1000 mm Hg) for leaks with the membrane guard in place and with the sensor in place and no leaks were found. To evaluate the integrity of the Safe-T-Seal bond, the assemblies were leak tested at 5 p.s.i. with neither a sensor nor a membrane guard in place. No leaks occurred. These leak tests are performed on 100% of the product produced by IBC. To test the functional suitability of the IBC Gas and Quick Cells, several hundred samples were tested in a simulated perfusion circuit using Human Blood Adjusted to the entire physiological range of perfusion conditions. The monitor readings were compared to a state of the art blood gas analyzer and to monitor readings recorded with CDI Cells. The results showed the same clinical performance when analyzed using accepted statistical methods. The IBC results are essentially identical to the CDI results and are summarized on the following graphs.

Conclusion

An exhaustive development and evaluation program was undertaken by IBC in order to produce a product that will perform to your expectations, improve the integrity of the assemblies, respect the patent position of our competitor, comply with the regulations promulgated by the FDA, and reduce the cost of quality health care. The result of this development is the IBC Gas Cell and Quick Cell product line. Whatever your concern might be in the selection of flow through cells for use in your CDI 300 or 400 Series Monitoring System, it will be satisfied by the IBC products.



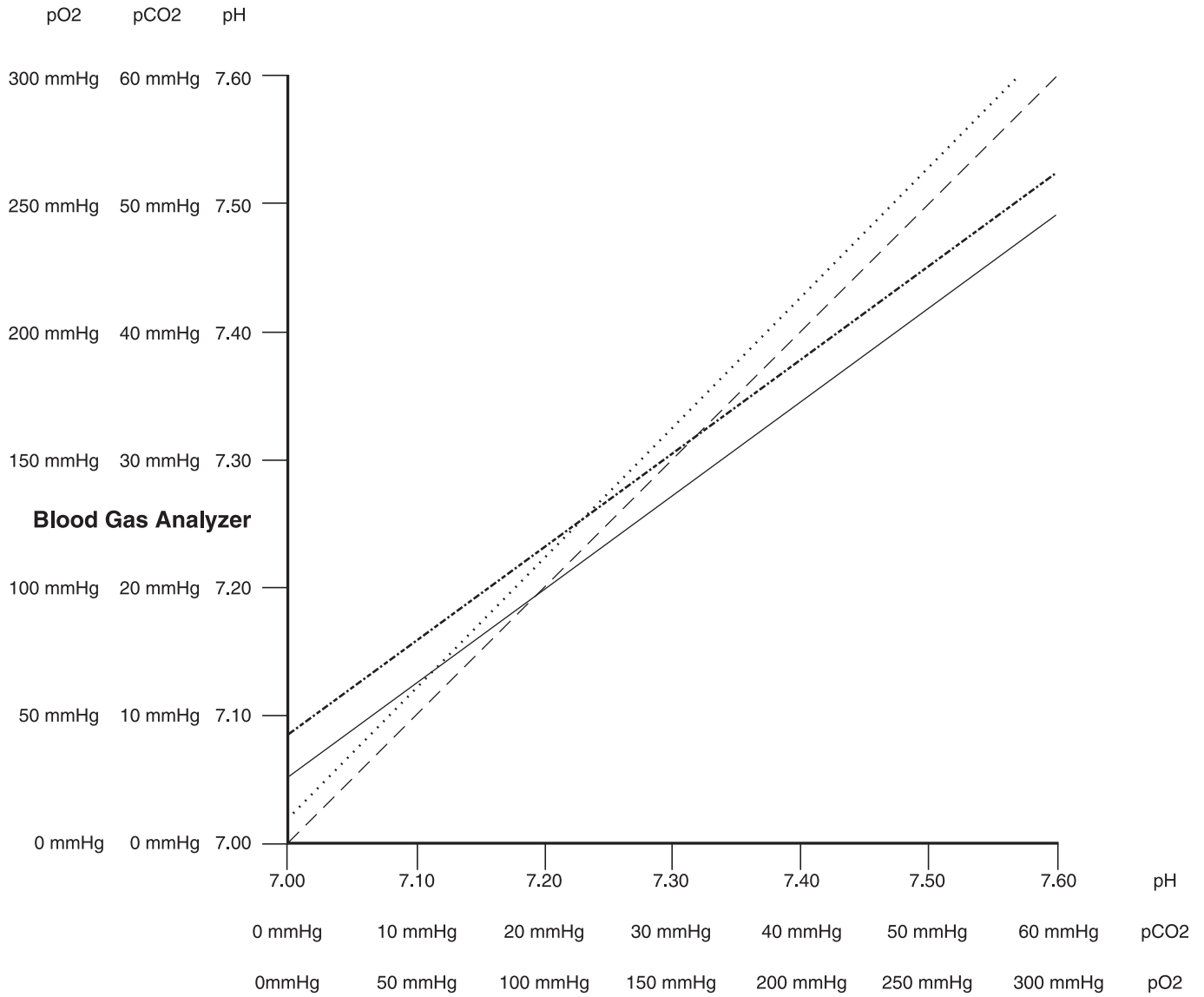
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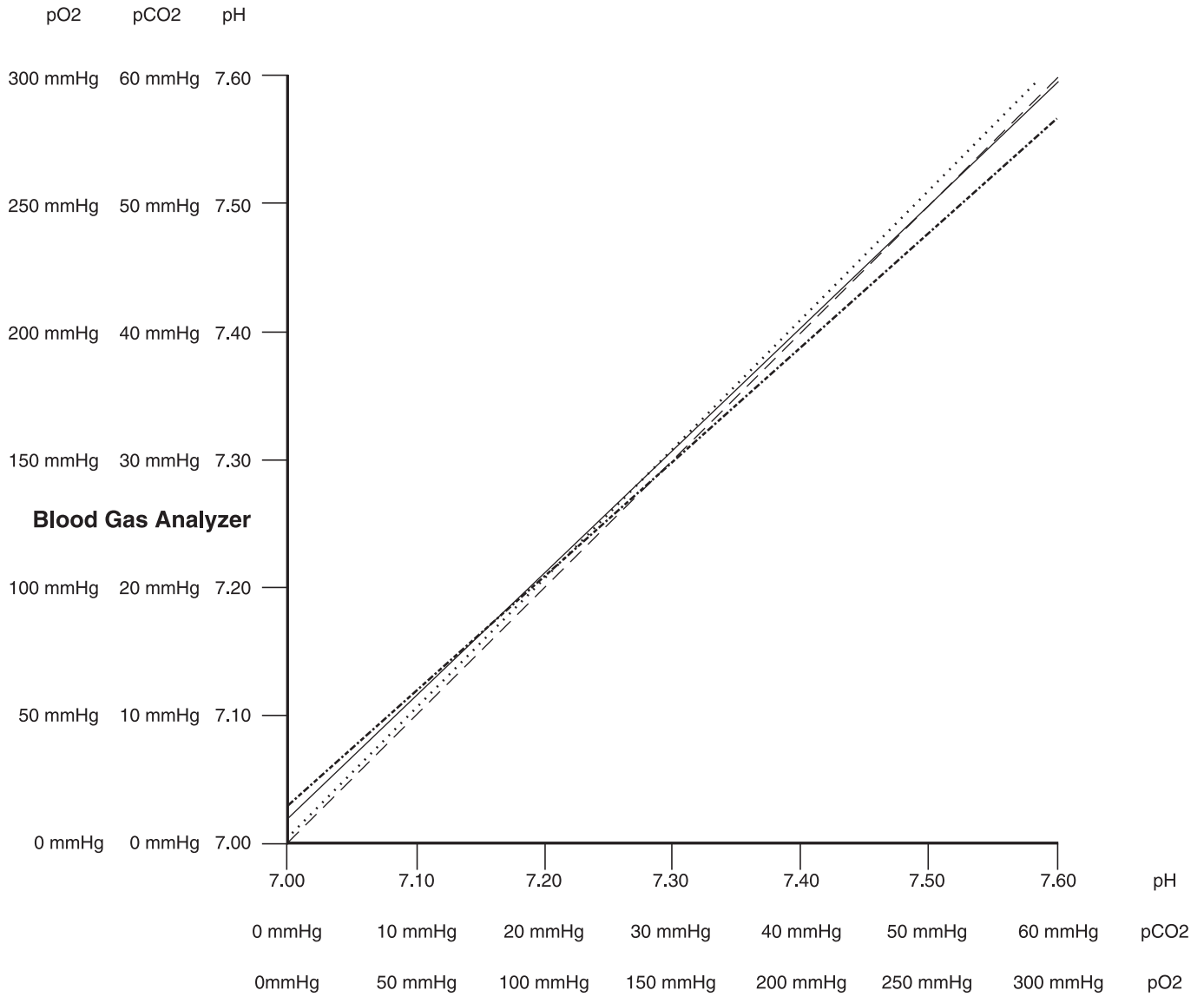
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CDI 300 Series Monitor With IBC Gas Cells *

- Idealized Plot** ----- **Correlation Coefficient = 1.000**
- Actual pO2 Plot** **Correlation Coefficient = 0.972**
- Actual pCO2 Plot** _____ **Correlation Coefficient = 0.835**
- Actual pH Plot** **Correlation Coefficient = 0.792**

*** The Test Data and Resultant Graph using CDI Gas Cells were essentially identical.**



CDI 400 Series Monitor With IBC Quick Cells *

- Idealized Plot** ----- **Correlation Coefficient = 1.000**
- Actual pO2 Plot** **Correlation Coefficient = 0.991**
- Actual pCO2 Plot** _____ **Correlation Coefficient = 0.982**
- Actual pH Plot** **Correlation Coefficient = 0.959**

* The Test Data and Resultant Graph using CDI Quik Cells were essentially identical.

Discussion

IBC considered the following issues in developing and testing its Gas Cell and Quick Cell product line:

Could we improve upon the 3M/CDI design so as to reduce the level of failures and leaks?

This was accomplished through the unique and patented IBC Safe-T-Seal design.

Would we be able to match the performance of the CDI Monitoring system after substituting the IBC Gas and Quick Cells?

This was achieved by using the exact same membranes from the same membrane manufacturer in the IBC Cells.

Could the IBC device be manufactured and sold without infringing any patents?

IBC received a formal opinion of non infringement on its design from a patent law firm. IBC was awarded a U.S. Patent on its unique Safe-T-Seal design after full disclosure of the 3M/CDI patents and other prior art. Furthermore, a Federal District court has ruled that the IBC Gas Cell and Quick Cell Products do not infringe the 3M/CDI Patent as a matter of law.

Do the IBC Gas and Quick Cell Products comply with all pertinent government regulations?

The IBC Cells meet or exceed all FDA requirements, and the IBC manufacturing facility and processes comply with EPA guidelines (the IBC products are made entirely without the use of solvents) and OSHA standards (IBC has had zero accident rate throughout its history).