Qfix Announces FDA 510(k) Clearance for SDX™ Automatic Gating Module™

New SDX Automatic Gating Module integrates respiratory gating with radiation therapy.


Until now, the SDX Spirometric Motion Management System used the voluntary deep inspiration breath hold (DIBH) technique to manage thoracic and abdominal tumor motion and only permitted the treatment beam to be manually operated. With the introduction of the new Automatic Gating Module, the SDX System now integrates respiratory gating with radiotherapy treatment using Varian’s Clinac® and Trilogy® platforms in addition to IBA’s Proton Therapy systems. This advancement allows the SDX System to automatically define beam-on and beam-off periods that are synchronized with a patient’s voluntary breath hold. The SDX™ System with Automatic Gating Module allows treatment beams to be more accurately directed to the tumor, potentially sparing healthy tissue and organs.

“We are pleased to announce clearance to market the SDX Automatic Gating Module in the U.S. and are extremely excited about this development,” said Dan Coppens, CEO and Technical Director of Qfix. “By extending the SDX™ system to active treatment beam gating, we will greatly enhance precision, ease of use, and patient comfort.”

Future developments will include the expansion of the automatic respiratory gating system to a variety of primary radiotherapy treatment systems. Further enhancements will increase the range of techniques and indications to which the SDX can be applied.

The SDX™ Spirometric Motion Management System and the SDX™ Automatic Gating Module has CE approval and FDA clearance.

About SDX™ Spirometric Motion Management System
The SDX™ is a voluntary breath hold system for managing thoracic and abdominal tumor motion during radiotherapy. The system uses a spirometer to monitor patient breathing in real time. When paired with voluntary deep inspiration breath hold (DIBH), the SDX™ System can suppress tumor motion, decrease treatment margins and reduce toxicity to vital organs such as the lung, heart and liver. SDX™ is a trademark of Dyn’R, SAS, France.

About Qfix
Qfix, headquartered in Avondale, PA, is a world leader in the design, manufacturing and marketing of radiotherapy patient positioning and immobilization devices. For more information about Qfix please visit www.Qfix.com.

Cautionary Statement Regarding Forward-Looking Statements
This news release may contain forward-looking statements based on current assumptions made by Qfix. These forward-looking statements are based on our beliefs, assumptions and estimates using information available to us at the time and are not intended to be guarantees of future events or performance. Qfix undertakes no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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