



Position Statement from Oakfield Instruments Inc in regard to the Health Insurance Portability and Accountability Act – HIPAA

This letter aims to present health care providers with information about the impact of the HIPAA regulations on utility of Oakfield Instruments' Flexilog range of motility recorders and in particular Flexisoft data analysis and capture software. The HIPAA regulations have raised many questions and concerns about whether software applications like Flexisoft are "HIPAA compliant".

The HIPAA statute covers a number of topics, of which there are two which present significant compliance issues for the healthcare industry as it relates to software applications like Flexisoft: privacy and security. Privacy regulations restrict the use and disclosure of medical record information and other individually identifiable health related information by the provider. Security deals specifically with protected health information in electronic form and requires providers to implement safeguards such as access controls to computer systems.

Although the phrase 'HIPAA compliant' has meaning when applied to software applications for billing and other electronic transactions, it is not meaningful in connection with software applications like Flexisoft as HIPAA does not regulate software. The statute imposes obligations upon the provider and other entities, but generally does not specify how those obligations should be met. A medical practice whose software does not provide for disclosure tracking but which has another tracking mechanism in place is not in violation of HIPAA. Similarly, most security requirements may be met by means of network-based controls, workstation controls or software controls.

Since HIPAA does not require software to include mechanisms for safeguarding protected health information, it falls upon the covered entity to safeguard the information in some way, but does not specify a mechanism. For most providers implementing security features on a application by application basis is not an efficient way to achieve HIPAA compliance, thus most providers have adopted reliable network and workstation security features. If these measures are well designed, providers will be HIPAA compliant while using Flexisoft in its present form. Some suggestions to implement privacy and security features while using Flexisoft are to select workstation and network-based solutions that implement password protected access to the applications and some type of audit capabilities to track user actions.

Oakfield Instruments will continue to monitor HIPAA and other regulations and strive to provide products that can be effectively integrated into a HIPAA compliant environment. Meanwhile, please contact Oakfield Instruments if you have any further questions about current Flexisoft software and HIPAA compliance.

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