

# Electronic Signature Compliance Statement

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## General

Title 21 Part 11 defines what the FDA determined to be the requirements for electronic signature of documents. These provisions include items that are necessary for both the electronic system to follow as well as outline necessary policies and procedures are in place to ensure that electronic signatures are valid. This document will outline how MagView addresses each of those requirements that are relative to the electronic system to help facilitate compliance with these regulations.

## MagView and Part 11

MagView is compliant with all electronic signature regulations. Furthermore, we are committed to continuing the development of MagView to remain compliant with any new requirements which may be enacted in the future. There are many features which facilitate compliance requirements of these regulations, including the user management system, user rights system and the MagView audit system.

The following table summarizes components of Title 21 Part 11, and the features of MagView which facilitate compliance with these requirements:

| <i>Citation</i>      | <i>Description</i>  | <i>Notes</i> |
|----------------------|---|--------------|
| §11.10(b)            | <b>Generation of Records</b><br>MagView allows facilities to produce patient records that contain electronic signatures in both printable and electronic form for inspection.                   |              |
| §11.10(c), §11.10(d) | <b>Record Protection</b><br>MagView allows facilities to protect patient records from access by unauthorized users via the user management system.  |              |
| §11.10(e)            | <b>Automated Auditing</b><br>MagView allows facilities to audit the entire system or each patient record or exam record using the MagView audit system. These records are stored for as long as |              |

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|                      | needed and thus will be retained for the required period.  |  |
| §11.10(g)            | <b>Record access</b><br>MagView only allows record access, reproduction or alteration to authorized MagView users that can be managed through the user management system.  |  |
| §11.50(a)(1),(2),(3) | <b>Signature Manifestations</b><br>MagView features allow compliance with all requirements relating to the structure of the electronic signature by allowing for the printed name of the signer, date of the signature and time of signature to be contained with the signature. |  |
| §11.50(b)            | <b>Inclusion of Signature</b><br>MagView features allow the signature manifestations cited above in §11.50(a)(1), (a)(2), and (a)(3) to be displayed in both human readable and electronic form.   |  |
| §11.70               | <b>Signature/Record linking</b><br>MagView features allow the electronic signature to be linked to their respective electronic records without the ability to excise, copy or transferred through ordinary means.  |  |
| §11.100(a)           | <b>Uniqueness of Signature</b><br>MagView features allow compliance with all requirements relating to the signatures unique nature.  |  |
| §11.200(a)(1)        | <b>Identification components</b><br>MagView features facilitate compliance with requirements for identification components by providing user login, password and PIN assignment through the user management system.  |  |
| §11.200(a)(1)(i)     | <b>Single Session Signatures</b><br>MagView features allow compliance with the requirements related to a series of signings during a continuous period of system access.   |  |
| §11.200(a)(1)(ii)    | <b>Multiple signings outside of single session</b><br>MagView requires users to log in before each session of system access, thus facilitating compliance with these   |  |

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|            | requirements.   |  |
| §11.300(a) | <b>Unique Nature of codes</b><br>MagView requires that each sign on have a unique personal code so that no two individuals may have the same combination of identification code and password. |  |
| §11.300(b) | <b>Aging of Password</b><br>MagView features allow facilitate compliance with the requirements of periodic password changes.  |  |
| §11.300(c) | <b>Interpreting Physician Continuing Experience</b><br>MagView allows facilities to document compliance with the requirements for interpreting physician continuing experience.               |  |

## More Information

Recognized as a leader in Mammography Information Management for more than 10 years, MagView offers scalable mammography software for mammography tracking, mammography reporting and MQSA outcome monitoring to meet the needs of every mammography department or practice. MagView is flexible enough to adapt to the requirements of your group, and powerful enough to efficiently automate your patient workflow.

For more information on MagView and the various products and services we have to offer, please visit [www.magview.com](http://www.magview.com) or call the MagView Support Department at 1.800.553.8996.