



IMCO-STAT FDA Approval

Document 4041 Revision A

INDICATIONS FOR USE

510(k) Number (if known): K063392

Device Name: IMCO-STAT™

Sponsor Name: IMCO Technologies

Indications for Use:

IMCO-STAT™ is a software device that receives digital images and data from existing imaging equipment using DICOM 3.0 communication protocols. Images and data are stored on the IMCO-STAT™ server in DICOM 3.0 Part 10 and JPEG format.

IMCO-STAT™ is designed to send reports, images, audio and video data to other workstations, Personal Digital Assistants (PDA) or Tablet PCs in wired or wireless environments. This is accomplished using an executable client application on a receiving entity with the appropriate hardware.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 Mpixel resolution and meets other technical specifications reviewed and accepted by FDA.



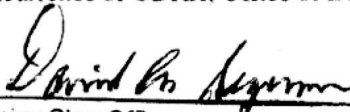
Prescription Use
(21 CFR 801 Subpart D)

And/Or

Over-The-Counter Use
(21 CFR 807 Subpart C)

Do Not Write Below This Line – Continue on Another Page if Needed

Concurrence of CDRH, Office of Device Evaluation



(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K063392

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