

AVIA™ - Computer Automated Proofreader for Drug Product Information Documents^{© 1}

Proofreading is a weak link in the delivery of accurate pharmaceutical product information to consumers and medical practitioners. Presently, human inspectors proofread pharmaceutical product information documents. This is a difficult job requiring painstaking attention to very fine detail for hours per document. In addition to being time consuming, proofreading by humans is error prone, mentally fatiguing, and requires a high skill level.

This document describes MNEMONICS' new computer automated proofreader – **AVIA** - for use in verifying that product information documents conform to their design in content and quality. In minutes, **AVIA** can find flaws and anomalies in production documents, printing plates and pre-press documents that are compared to a master document (electronic or printed). The flaws are then presented for corrective action to quality control or production personnel. Human review of **AVIA**'s results requires a fraction of proofreading time (5 to 10 minutes versus several hours), significantly improving inspector efficiency and performance and also reducing fatigue.

AVIA improves the accuracy of information distributed to consumers and as a result reduces the potential for human harm or death. For manufacturers, product cost, waste, and liability risks are diminished. The ultimate objective of **AVIA** is to ensure high quality, error free pharmaceutical product information distribution.

¹ Adapted from a presentation by Dr. Michael Negin at Interphex, March 2003, Jacob Javits Center, New York, NY

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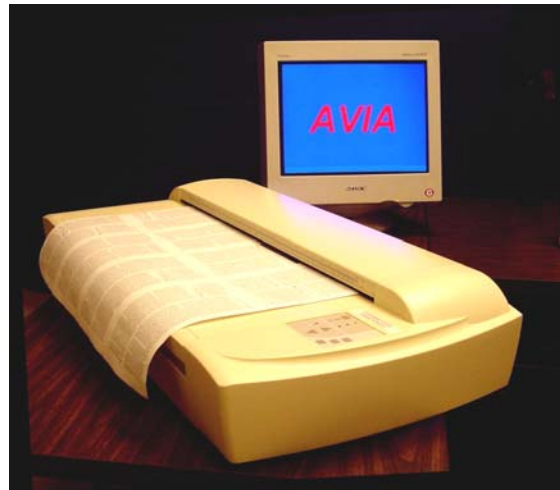
THE GOAL

Reduce or eliminate printing errors in product information documents that are distributed to consumers and medical practitioners



THE AVIA SOLUTION

Using proprietary computerized visual information processing, state-of-the-art high-resolution large sheet scanners, and high-speed computer processing, **AVIA** detects print errors while discriminating against distortions caused by paper stretch and bleed-through. This technology replaces the human visual system in identifying potential defects.



AVIA System

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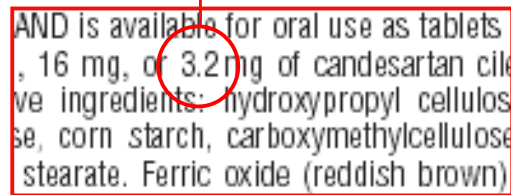
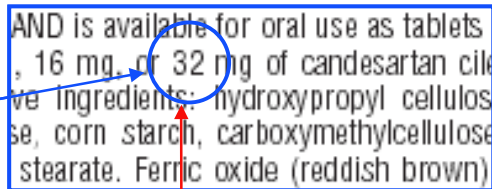
AVIA detects very small flaws in large document images.

The figures below show a Pharmaceutical Product Sheet and the results of AVIA inspection processing. The image size is 15,000 x 12,000 pixels (180,000,000 pixels). The AVIA processing finds the 5 pixel error in the text. Errors of this type can be the cause of incorrect medication, harm to the consumer, and expensive product liability proceedings. The processing of the entire document is accomplished in less than one minute vs. hours for a human inspector.

Master Document

Product information for candesartan cilexetil tablets, including sections for Indications, Dosage, Contraindications, and Warnings. The document is a standard pharmaceutical product sheet.

Magnified area of Master Document shows correct number is "32".



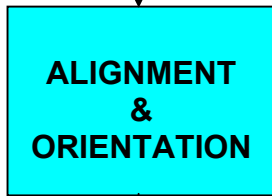
Magnified area of Production Document which has been compared to the Master Document by AVIA shows "3.2" has erroneously been printed.

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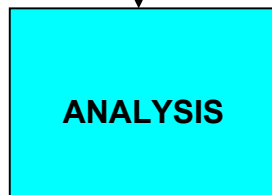
HOW DOES AVIA WORK?



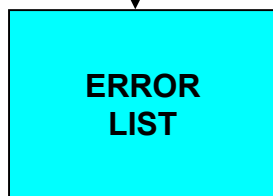
A large format scanner is used to read in the product information document.



AVIA's specialized proprietary software aligns and orients the document and the reference document. The software also corrects for paper stretch and bleed through.



The system inspects the characters in the document as well as graphics, chemical formulae, charts, and pictures. All disparities greater than a user-specified size and intensity are located and marked as flaws.



AVIA ranks and tabulates flaws. An Internet compatible (HTML) document is produced for human review and subsequent document management.

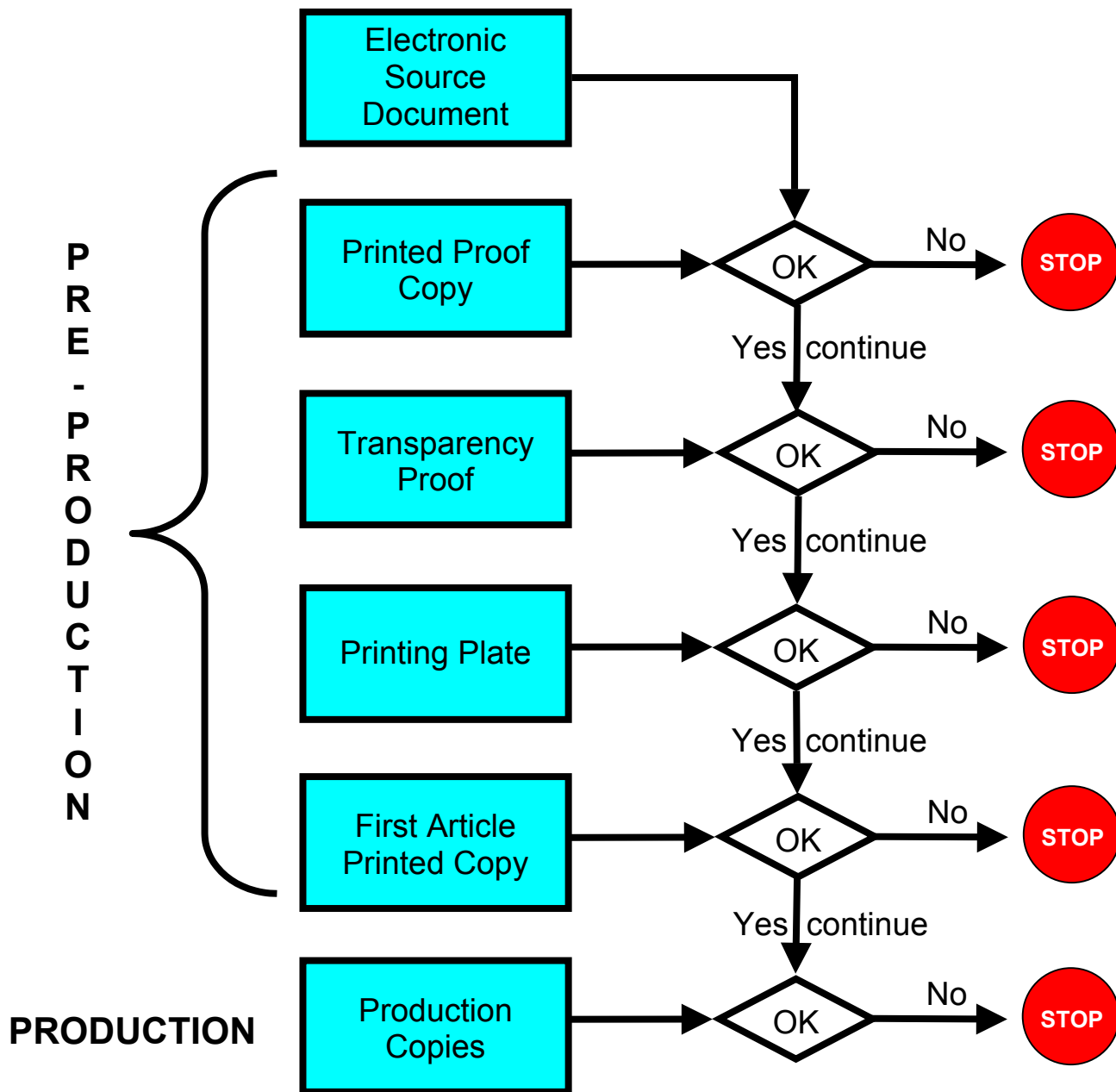


A human operator reviews the generated error report, annotates the report, and initiates corrective action as needed. A final report can be generated for record keeping.

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Document Production Flow

AVIA can be used in all phases of production document generation, from pre-press electronic document comparison and preparation to print quality inspection during production runs.



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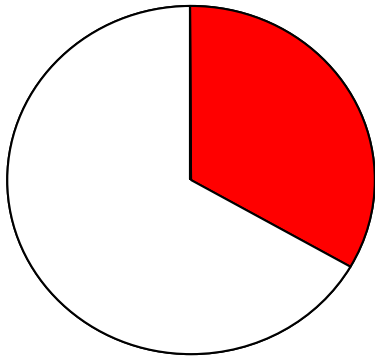
HOW WELL DOES AVIA WORK?

Error Performance

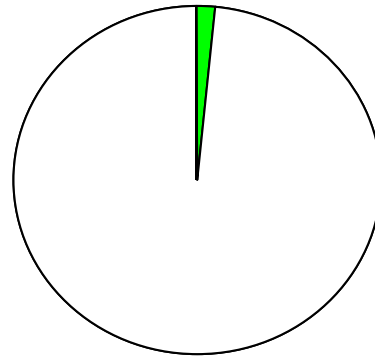
- Human proofreaders can miss critical errors.
- **AVIA** performs a more detailed proofreading in only a few minutes, and finds every flaw.

Time Performance

- **AVIA** is approximately 200 times faster than human proofreading. Specifically,
 - 1 to 3 minutes to scan a document
 - Defects processed and categorized by the system in about 40 seconds for a large document (22 x 17 inches).
 - About 5 minutes for human review



Human Inspectors:
Up to 4 Hours to Review



AVIA:
Approximately 7 to 10 Minutes

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COMPETITIVE PERFORMANCE

- **AVIA** uses newly developed image comparison techniques that correct for stretching & shrinking of paper throughout the document. **AVIA** corrects for non-uniform stretching that occurs during the printing process due to paper tension variation on the presses resulting in vastly improved accuracy.
- **AVIA** processes the whole document as a single image & doesn't 'stitch' together a mosaic of the document like other systems that capture multiple small images from a low resolution camera. This results in much improved flaw detection performance.
- **AVIA** produces a "web page" style report that can be shared within a company intranet, private networks or via the Internet.
- **AVIA** can compare electronic vs. electronic documents, which is valuable during prepress document generation.
- **AVIA** can compare electronic or print documents to print documents, which is required for production print quality inspection.
- **AVIA's** high speed comparison technology can reduce document review time by up to 90% and can assist human reviewers to find re-flow and print errors accurately and rapidly.

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