

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF MASSACHUSETTS

IN RE: FRESENIUS	)	
GRANUFLO/NATURALYTE DIALYSATE	)	
PRODUCTS LIABILITY LITIGATION,	)	
	)	
This Document Relates To:	)	
	)	MDL No. 1:13-md-02428-DPW
ALL CASES	)	
	)	

**CASE MANAGEMENT ORDER No. 12**  
**(Order Governing the Format of Generic Document Production)**

With regard to the procedures and format relating to the production of documents and things by Plaintiffs and by defendants Fresenius Medical Care Holdings, Inc. d/b/a Fresenius Medical Care North America, Fresenius USA, Inc., Fresenius USA Manufacturing, Inc., and Fresenius USA Marketing, Inc. (collectively, "FMCNA"); and Fresenius Medical Care AG & Co. KGaA, Fresenius Medical Care Management AG, Fresenius SE & Co. KGaA and Fresenius Management SE (collectively, the "European Fresenius Defendants") in response to generic requests for discovery, the Court hereby Orders:

**A. GENERAL**

1. In the event this Order does not otherwise provide for the method of production, the parties shall meet and confer in good faith on a manner of production that balances the needs for production to be efficient, cost effective and reasonably useable.

2. Except as specifically limited herein, the Order governs the production of discoverable documents by Plaintiffs and by FMCNA and the European Fresenius Defendants during generic discovery in this Litigation as set forth at paragraph 2 of Case Management Order No. 2. A protocol for the production of discoverable documents for case-specific discovery on a going forward basis will be the subject of separate discussion and, if necessary, additional Case Management Order(s).

3. All documents that are responsive to generic discovery requests will be produced, subject to objections and responses, and subject to the parties' Protective Order and/or Confidentiality Order, in the manner provided herein.

**B. PRODUCTION PROTOCOLS**

4. General Format of Production. All documents produced pursuant to generic discovery requests in this litigation shall be produced as electronic TIFF images with associated text (OCR or extracted text as set forth herein), metadata, and objective coding, unless another production format is designated herein or otherwise agreed to by the parties.

5. Production of Electronic Images and Associated Data. Except as limited in this paragraph or as described herein and/or as otherwise agreed to by the parties, all documents that originally existed in electronic or hard-copy form that are produced in these proceedings shall be produced in electronic image form in the manner provided herein. To the extent exceptions to the foregoing are required, the parties will meet and confer to discuss alternative production requirements, concerns, or formats. Except for redacted documents, each document produced pursuant to this Order shall convey the same information in the electronic image(s) produced as the original document. Documents that present other imaging or formatting problems shall be promptly identified by the receiving party and the parties shall meet and confer to attempt to resolve the problems.

a. Document Image Format. All production document images, whether scanned from hard copy documents or generated from native electronic documents, shall be provided as single-page Tagged Image File Format (".tiff format"), using Group 4 compression at 300 dpi resolution, and shall reflect, to the extent practicable, without visual degradation, the full and complete information contained in the original document, unless redacted. Reasonable efforts will be used to scan the pages at or near their original size and so that the image appears straight and not skewed. Physically oversized originals, however, may appear reduced. In addition, reducing image size may be necessary to display Bates numbers without obscuring text. Unless otherwise indicated by this or other Case Management Orders or as agreed between the parties, the documents shall be produced in accordance with Rule 34 of the Federal Rules of Civil Procedure. The parties shall meet and confer to the extent reasonably necessary to facilitate the import and use of the produced materials with commercially available document management or litigation support software.

b. Load Files: Load file means an electronic file provided with a production set of document images that facilitates the loading of such information into a receiving party's document review platform, and the correlation of such data in the platform. A properly delimited ASCII text file containing Metadata and any objective coding required to be provided pursuant to this Order, an IPRO (LFP file) or OPTICON load file for tiff images, and document level ASCII OCR or Extracted text files named with the corresponding StartBates or BegBates document ID. The receiving party will provide the producing party with load file specifications 14 days in advance of the date of the first production. The producing party will have the right to request a sample load file and deliver a small first production to ensure the load file works and avoid any unnecessary costs associated with a faulty large-scale production.

c. Document Unitization. Each page of a hard copy document shall be scanned into an image and if a document is more than one page, the unitization of the document and any attachments shall be maintained as it existed in the original when creating the image file. For documents that contain fixed notes, the pages will be scanned with the notes and those pages will be treated as part of the same document. Post-it notes should be removed prior to scanning and scanned as a separate page immediately following the page it was attached to. The relationship of documents in a document collection (e.g., cover letter and enclosures, email and attachments, binder containing multiple documents, or other documents where a parent-child relationship exists between the documents) shall be maintained. If more than one level of parent-child

relationship exists, documents will be kept in order, but all will be treated as children of the initial parent document. Such information shall be produced in the load file and metadata or objective coding, as set forth herein, in a manner to enable the parent-child relationship among documents in a document collection to be reconstituted by the receiving party in commercially available document management software, such as Concordance. All documents produced shall have a character that delineates page breaks in the OCR text so that the receiving party can determine where one page ends and another page begins. Parent-Child as well as other document family relationships and document unitization relationships shall be maintained even if that results in the production of documents considered to be duplicate documents as defined in paragraph B(5)(e) below.

d. Color. If an original document contains color, the producing party shall not deny reasonable requests for color copies of the original. Upon receipt of a request for a color copy of a document originally produced in black-and-white, the producing party shall provide a replacement image and load file bearing the same Bates number for that previously produced document with its next production.

e. Duplicates. Each party will take reasonable steps to de-duplicate electronic documents and other ESI in accordance with the terms of this Order. The parties will de-duplicate data within a custodian for all sources (i.e., custodial de-duplication or vertical de-duplication). Near duplicates or similar documents will be produced. Duplicated electronic files will be identified based upon calculated MD5 Hash values for binary file content using industry standard tools. For electronically stored information that is not email: contents only will be used for MD5 Hash value calculation and will not include operating system metadata (filename, file dates) values. For email, certain email metadata such as the To, From, CC, Subject, Body, and binary streams of all attachments will be used for MD5 Hash value calculation. All files bearing an identical MD5 hash value make a duplicate group.

f. Messaging Files: Duplicate messaging files will be identified based upon MD5 Hash values for the message family, including parent object and attachments. Duplicate messaging materials will be identified at a family level, including message and attachment(s).

g. Bates Numbering and Source Index. Each page of a produced document shall contain a legible, unique identification number ("Bates number") and confidentiality notice, where applicable, which will be electronically burned onto the page image in a manner that does not obliterate, conceal, obscure, or interfere with any information from the source document. No other stamp or information will be placed on a document other than Bates-number, confidentiality notice, and any redactions as may be required. This provision does not apply to databases or documents produced in native electronic format.

h. File Naming Conventions. Each page image file shall be named with the unique Bates number of the page of document, followed by the extension ".TIF." In the event the Bates number contains a symbol and/or character that cannot be included in a file name, the symbol and/or character will be omitted from the file name.

i. Production Media. Document productions will be made by electronic transfer, or on CD-ROM, DVD, external hard drive, or such other readily accessible computer or electronic media as the parties may hereafter agree upon (the "Production Media"). Each piece of Production Media shall be marked with a specific identifying number, like a Bates number, as well as the following: production number, production date, and the Bates number range(s) of the materials on the Production Media.

j. Metadata: Metadata means corresponding data about an electronic document that is generally not seen on the face of the document or when the document is printed (e.g., date created, date sent, author, recipient, etc.). For electronic documents, e-mails and hardcopy documents, the parties agree to produce objective coding and metadata as set forth in "Attachment A", to the extent such coding and/or metadata is responsive, not privileged, not subject to applicable foreign privacy and data protection laws, available and applicable. The producing party may redact, or remove from production, protected and/or privileged metadata, so long as all revisions or redactions, if made for purposes of attorney-client privilege or work product protection, are individually noted on the privilege log.

k. OCR/Extracted Text: The producing party shall produce corresponding Optical Character Recognition (OCR) text files for hard-copy documents and any electronic documents that require redaction prior to production. For electronic documents that require redaction, the process shall be that the producing party shall export the document to a TIFF image and perform the OCR process off that TIFF image. Printing electronic documents to paper for the purpose of performing the OCR scan shall not be permitted by this Order. When subjecting physical documents to an OCR process, the settings of the OCR software shall maximize text quality over process speed. Settings for "Auto-Skewing" and "Auto-Rotation" should be turned on when documents are run through the process. For documents that exist in electronic format that have not been redacted and that are produced as images, the producing party shall produce extracted text files reflecting the full text that has been electronically extracted from the original, native electronic files. The parties shall coordinate regarding the specifics for delivering OCR and extracted text as part of productions, including any load files specifications. For any document that will undergo the OCR process and contain a redaction, the producing party shall burn a Bates number onto the image or document prior to the OCR process such that the Bates number becomes part of the OCR file. In the event the Producing Party updates the OCR to include the production Bates numbers into the OCR text for its own use, the producing party shall provide an identical production to the Receiving Party.

l. Native Format Productions. Native production means electronic documents that are produced in the format in which they were created and used (also referred to in terms of "Native Format"). A receiving party may, after receipt and review of documents produced in .tiff format pursuant to this Order, request that specific Excel spreadsheets and other documents be provided by the producing party in native format. Any such reasonable request will not be denied. The parties agree that any documents produced in native format will be given the same level of confidential protection as is due the originally produced document under CMO no. 5 regardless of whether the document in its native format contains a confidentiality designation. Any native files that are produced shall be produced with a Bates-numbered TIFF image slip-sheet stating "Document [Begin Bates number] to [End Bates number] is a [document type] that has been

produced in native format." The slip-sheet shall also contain a MD5 hash generated for the produced native file. Any native files that are produced shall be produced with the source file path provided, as well as all extracted text and applicable metadata fields set forth in Attachment A. Spreadsheets that require redactions will be converted to TIFF images as follows: remove user-defined print areas; unhide and expand all columns, rows and sheets; expand/outline groupings; print to TIFF each sheet across (left to right) and then down; set for landscape orientation; and remove blank pages as possible. Any autodate macros will be indicated as "<autodate>".

m. Databases. The parties shall meet and confer concerning the scope and production format for discoverable information contained in databases and other structured data sources. Such production shall be governed by separate stipulation of the parties or Order of the Court.

n. Video, Audio, other electronic media that cannot be rendered as Tiff images. Except as subject to redaction or other protection, the producing party shall produce requested relevant video, audio and other electronic media that cannot easily be rendered as Tiff images in their original media format, i.e., CD Audio, DVD Video, etc. unless the original format is unreasonable, or unduly burdensome or costly, in which situation the parties will meet and confer on the format for producing this type of information. Audio and video files may be edited, only after consultation with the opposing party, if redactions are required, subject to appropriate identification of any such modification to the original audio or video file.

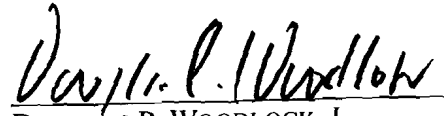
o. Original Documents. The producing parties shall retain the original hard-copy and native source documents in their original format (together with, except as may be otherwise expressly agreed among the parties, the means to access, retrieve, and view such documents) for all documents produced in this proceeding. Producing parties shall maintain the original native electronic source documents in a manner so as to preserve the "metadata" associated with these electronic materials in the event review of such metadata becomes necessary. Subject to preservation of appropriate privileges and other protections of the producing party's information from production in accordance with applicable law, upon a showing of good cause or particularized need, after reasonable request and any necessary meet and confer, where a document existed originally in only hard copy format, the producing party will make originals of any produced document available for inspection by the requesting party in the form in which such documents are kept in the ordinary course of business.

6. Replacement Images. If a document produced by a producing party has an error or the images must be replaced due to inadvertent or mistaken production, a change in confidentiality, or other reason the replacement production must be marked as a replacement, and the producing party must provide a reason for the replacement. The load file of the replacement document(s) must be separately produced in a complete replacement file, which contains the replacement document(s) only.

7. Disputes: The parties will meet and confer in good faith, and endeavor to resolve any dispute related to this Order before submitting such disputes to the Court for determination.

8. Relief and Modification: After an appropriate meet and confer in good faith, either party may apply to the Court for relief or modification of this Order.

**SO ORDERED** this 19th day of June, 2014.

  
DOUGLAS P. WOODLOCK, J.

