

Device Modification Analysis Summary

Ref no.: DMA 2004/09

Part I. Product Information/Description of Change

Product: DRYPIX 4000 Medical Dry Laser Imager

Predicate Device Name & 510(k) #: DRYPIX 7000/5000 Medical Dry Laser Imagers (K033377)

Description of Change:

The DRYPIX 4000 represents a modification of the above cleared device. The DRYPIX 4000 uses the same laser exposure technology, thermal development technology, film conveyance layout and imaging film as the DRYPIX 7000/5000. It also has the same indications for use as the DRYPIX 7000/5000 including the printing of digital mammography images (FFDM). It differs in component layout, more accessibility for released and jammed films and it is also designed to withstand vibration and shocks in a mobile environment. Other similarities and differences are documented in the attached SE Feature Comparison table.

Part II. Device Modification Analysis Checklist

1. Could the change or modification significantly affect the safety or effectiveness of the subject device? **No**
2. Is there a significant change to the design, material, chemical composition, energy, or manufacturing process? **No**
3. Is there a significant change to the intended use of the subject device? **No**
4. Is there a significant change to the labeling (i.e. Warnings, additional claims) which may affect the safety or effectiveness of the device? **No**

Part III. Attached Documentation

Please list below and attach any documentation used to support this Device Modification Analysis.

1. Regulatory Action Determination Flowchart for DRYPIX 4000
2. Ruby (DryPix 4000) Specifications, dated 8/24/2004
3. Ruby (DryPix 4000) Specifications Supplement, dated 8/24/2004
4. Substantial Equivalence (SE) Feature Comparison Table

Ref no.: DMA 2004/09

PLEASE CHECK ONE:

The above information has been reviewed and it has been judged that Fuji has no pre-market obligations to the FDA for the subject device and marketing of the device may begin immediately, subject to the general controls imposed by FDA for such a device.

A more detailed narrative for this decision shall be documented either in the comment section below or in attached documentation (such as a memo, letter, etc.).

It has been determined that a pre-market obligation exists, therefore a 510(k) pre-market notification shall be filed by FMSU and cleared by FDA prior to marketing of such a device.

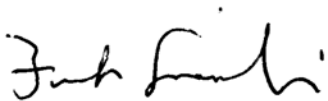
A more detailed narrative for this decision shall be documented either in the comment section below or in attached documentation (such as a memo, letter, etc.).

Comments:

The DRYPIX 4000 is considered a modification of the previously cleared DRYPIX 7000/5000 Dry Laser Imagers. The modification consists of technology and/or performance changes. Based on this evaluation, it appears that these changes (1) do not affect indications for use, (2) do not require clinical data to evaluate safety and effectiveness, and (3) do not raise new issues of safety and effectiveness.

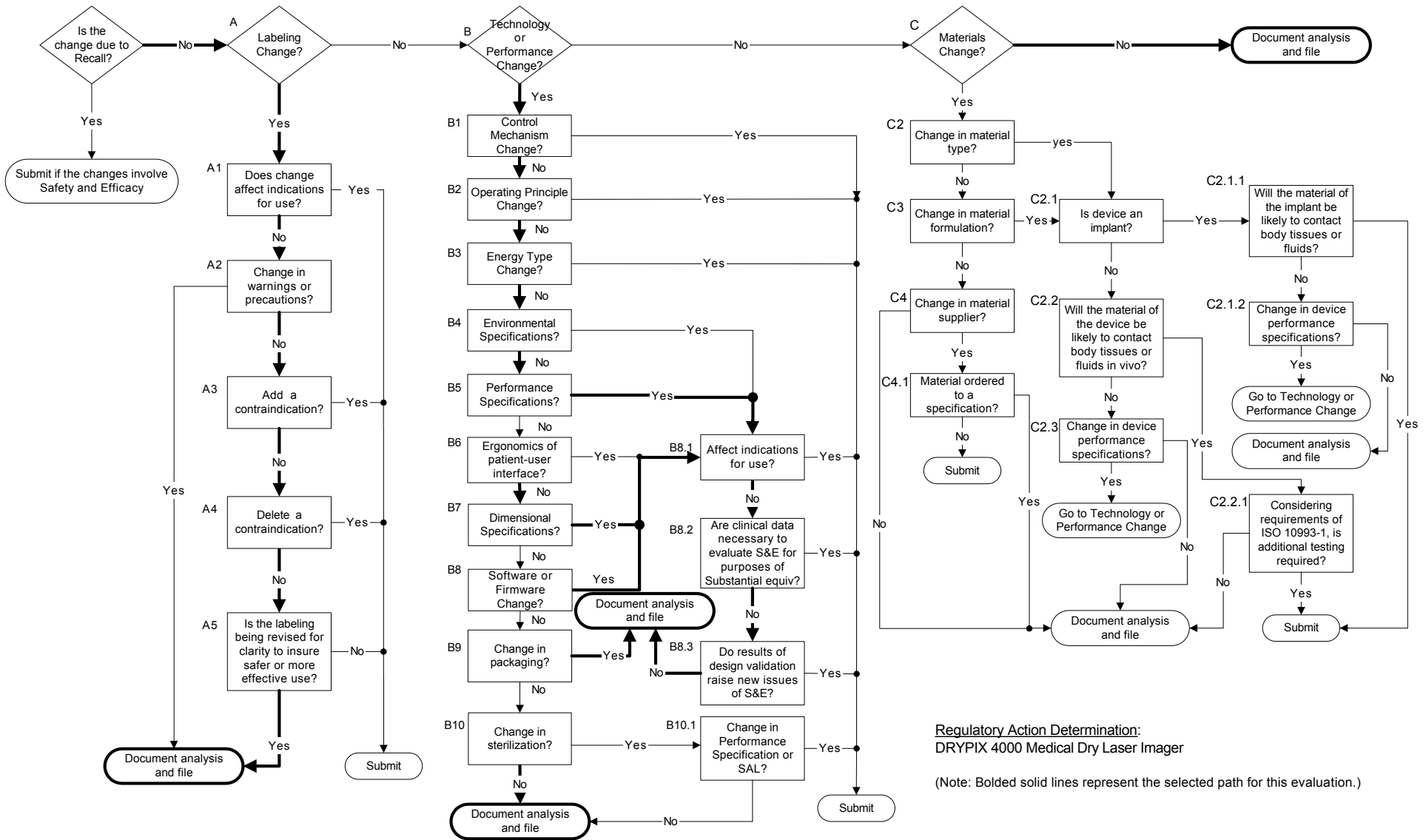
Therefore, it is my conclusion that the DRYPIX 4000 does not change indications for use nor does it significantly affect any safety or effectiveness issues than what is already identified in the premarket notification for predicate devices, DRYPIX 7000/5000. Therefore, I have reached a conclusion that the DRYPIX 4000 represents a modification that does not require a 510(k) submittal.

QARA SIGNATURE:



Frank Gianelli
Regulatory Coordinator

November 15, 2004
Date



Specifications of Ruby

Classification	Customer Requirement Specification & Other Requirements		Design Input		Product Specifications (See main text for details)
	CRS No.	Requirements	Design Input No.	Items	
1. Functional Requirements	Req - Ruby - 01	Number of trays for film supply is increased after installing the main unit and two different size trays can be used simultaneously.	Req-Ruby-01-01	Number of trays for film supply	Two trays are available. The upper tier tray is normally equipped. The lower tier tray is optional (Future addition is available on the market). Any size of films can be selected according to each tray. Size of tray is set by the qualified service personnel (as Service Setting).
		A pack of films can be accumulated on the specified loading part.	Req-Ruby-01-02	Number of accumulable films on the specified loading part	Up to 150 sheets of films can be accumulated to store them.
		Printing function of annotation strings comparable with the conventional DRYPIX7000 is equipped.	Req-Ruby-01-03	Printing function of annotation strings	Annotation strings can be printed out on the upper portion and lower portion of a film. Normal character size (40 pixels for standard), twice, three times and four times each that of normal character size can be set. The annotation strings can be indicated in accordance with DICOM Annotation BOX SOP Class or by setting configuration via PC utilities. Alphanumeric, Japanese, and Chinese characters can be indicated as readable strings. Conversion function of macro characters [reception date of printing, sender's IP address, identifier (optional string corresponding to IP address), and AE-title] is employed. This system can translate to print out such annotation strings of image format in accordance with DICOM Annotation BOX SOP Class.
		The test patterns comparable with the conventional DRYPIX7000 can be output.	Req-Ruby-01-04	Test patterns printing function	The 24-steps densitometry pattern, 17-steps densitometry pattern, QC test pattern, and SMPTE test pattern can be output to control the density. The flat test pattern can be output to check the nonuniformity. The sharpness and the double density/sharpness test patterns can be output to measure the sharpness. The lattice test pattern can be output to adjust the format. The uniformity test pattern can be output to adjust the uniformity.
		Sufficient security system functions.	Req-Ruby-01-05	Security measures	The Operating System can be updated as Service function. A anti-virus software can be installed as Service function. The pattern file of the anti-virus software can be updated by users. Images stored in HDD (e.g. to reprint images and to copy any image data to the other media) can be printed out only when the registered user gives the authentication.
	Req - Ruby - 02	Sorter attaching not less than 3 bins can be mounted for future additions.	Req-Ruby-02-01	Number of sorter bins	Three-bin sorter unit is available to set as an optional for future addition. Totally, four-bin sorting together with a tray equipped with the main unit can be allowed. The numbering of the bins with the configuration setting via PC utilities is allowed in an up to down order, and vice versa.
			Req-Ruby-02-02	Number of films accumulable on each sorter bin	Up to 30 sheets of films can be accumulated. Bins should be made of suitable materials to avoid scratching the film surface when films are taken out of such bin.
			Req-Ruby-02-03	Types of Sorting	The following sorting types are available: To output films to the desired bin by designating the bin number complying with DICOM; to output films to such bin specified by each AE-title via configuration setting; and to output films to such bin by specifying each film size via configuration setting.
			Req-Ruby-02-04	When a sorter fails	When a sorter fails, the user will remove it to release films to a tray of the main unit via the control panel. When a tray of the main unit fails, films will be output to the uppermost sorter bin.
			Req-Ruby-02-05	Sorter fitting position	Fit a sorter to the film release unit.
2. Performance Requirements	Req - Ruby - 03	This System reduces restraints on installation by applying 100V power source, the space saving function, and the like more easily in comparison with DRYPIX7000.	Req - Ruby - 03-01	Size of Unit	Main unit only W 600×D 550×H1000 to W 630×D 600×H1100 Main unit with sorter W 600×D 550×H1300 to W 630×D 600×H1400 ※Width and depth of the floor dimension don't include a locally protruding area.
			Req - Ruby - 03 - 02	Weight	Main unit only 130 to 150Kg Main unit with sorter 135 to 180Kg
			Req - Ruby - 03 - 03	Power supply voltage	AC100 to 120V±10% 12A or less AC200 to 240V±10% 7A or less
			Req - Ruby - 03 - 04	Voltage source capacity	1.2kVA or less
			Req - Ruby - 03 - 05	Environmental working condition (operating)	Temperature 15 °C to 30°C Humidity 15 % to 70%RH (No dew condensation) Atmospheric pressure 700 to 1060hPa
			Req - Ruby - 03 - 06	Environmental working condition (non-operating)	Temperature 0 °C to 45°C (Avoid freezing) Humidity 10 % to 90%RH (No dew condensation) Atmospheric pressure 500 to 1060hPa
			Req - Ruby - 03 - 07	Floor (installation surface)	Floor vibration condition : Complying with Fuji's Medical Device Quality Standards (K12N0097A) Floor levelness : 10 mm/m in all directions (1/100 or less of gradient) Floor flatness : 10mm or less
			Req - Ruby - 03 - 08	Ventilation condition	Ventilation in an area where the system is placed: 54m ³ /h or less per system (Equal to or lower than that of DRYPIX7000)
			Req - Ruby - 03 - 09	Antimagnetic field	The system normally operates at DC 100 Gauss without any problem.
	Req - Ruby - 04	This System can be installed in a Mammography Screening Mobile (When an optional component is mounted).	Req - Ruby - 04 - 01	Vibration condition when loading it on the mobile (When moving)	Random vibration: 5 to 500Hz, X, Y, and Z axis: 24 hours each Totally 72 hours (300000 km assumed) Acceleration: 1G
		Req - Ruby - 04 - 02	Vibration condition when loading it on the mobile (When operating)	References for Operating Vibration & Shock of the Medical Device Quality Standards (K12N0097A)	

Specifications of Ruby

Classification	Customer Requirement Specification & Other Requirements		Design Input		Product Specifications (See main text for details)
	CRS No.	Requirements	Design Input No.	Items	
			Req - Ruby - 04 - 03	Environmental condition (temperature & humidity) when loading it on the mobile	The system normally operates under the conditions specified in Section Req-Ruby-03-05. It is assured that the system can normally operate after reaching the above environmental conditions by rising temperature levels starting from - 10°C in a Mammography screening mobile.
			Req - Ruby - 04 - 04	Start-up time	From 15 min. (When starting up at 15 – 30°C) to 90 min. (When starting up at -10°C)
		The specific level of image quality and stability comparable with or more than DRYPIX7000/DI-HL system is kept. In combination with FCR PROFECT CS, this System is applicable to mammography screening.	Req - Ruby - 05 - 01		14 bits
			Req - Ruby - 05 - 02	Maximum density (Dmax)	Maximum density can be adjusted (by designating a level under DICOM or by setting configuration) using a density correction table as follows: When $D_{max} \leq 3.0$, the $D_{max}3.0$ table is used; when $3.0 < D_{max} \leq 3.3$, the $D_{max}3.3$ table is used; and when $3.3 < D_{max} \leq 3.6$, the $D_{max}3.6$ table is used.
			Req - Ruby - 05 - 03	Size of recording pixel	100 μ m \pm 0.5% (standard) / 50 μ m \pm 0.5% (optional) 14"x17" films and 14"x14" films also can be recorded at 50 μ m. The system can carry out 100 μ m recording in "STANDARD" mode and 50 μ m recording in "FINE" mode. ("STANDARD" and "FINE" are DICOM Requested Resolution IDs.) The system having two AE-titles (for 100 μ m & 50 μ m recording) above as DICOM PrintSCP can carry out recording in compliance with the designated AE-title.
			Req - Ruby - 05 - 04	Maximum number of pixels for recording	(In case of 100 μ m recording) 14"x17" film: 3520×4280 14"x14" film: 3520×3520 10"x14" film: 3600×2540 8"x10" film: 2000×2510 10"x12" film: 3016×2506 (In case of 50 μ m recording) Twice as many as the number of pixels described above on both main and sub scanning. CR images are recorded at the maximum number of recording pixel. Any images other than CR images defines a recording area at a same size in a manner as a printing area of annotation strings is subtracted from the max. number of recording pixels to format.
			Req - Ruby - 05 - 05	CTF	c/mm Main Direction 94% or more 75% or more Sub-direction 94% or more 75% or more 2.5 5.0
			Req - Ruby - 05 - 06	Density dispersion within a film	$\Delta D \leq 0.1$ (at OD=1.2)
			Req - Ruby - 05 - 07	Nonuniformity / Flaw	Any nonuniformity or flaws does not affect the diagnosis. Any problems on image quality does not arise. The limit samples for nonuniformity is specified according to a nonuniformity type.
			Req - Ruby - 05 - 08	Point defects	Size of Point defect Specifications Under 0.2mm 5 or less / 10*10cm 2 or less / 1*1cm 0.2mm or more None
			Req - Ruby - 05 - 09	Dimensional accuracy of image	Dimensional accuracy of overall width : $0 \pm 0.5\%$ Dimensional accuracy of each part : $0 \pm 0.6\%$
			Req - Ruby - 05 - 10	Curl after development	Keep a film curl level within 20mm or less from the surface of radiographic film illuminator.
			Req - Ruby - 05 - 11	Accuracy of density correction	Density correction within the following accuracy is available: Gradient end characteristic (Fog \leq OD < 0.3) same as FL-IM D $\Delta D = \pm 0.05$ or less (0.3 \leq OD < 2.0) $\Delta D = \pm 0.07$ or less (2.0 \leq OD < 2.7) $\Delta D = \pm 0.10$ or less (2.7 \leq OD < 3.0) $\Delta D = \pm 0.20$ or less (3.0 \leq OD \leq 3.6)
			Req - Ruby - 05 - 12	Density change due to development	$\Delta D = \pm 0.05$ (at OD=1.2)
			Req - Ruby - 05 - 13	Exposure temperature & humidity dependency	$\Delta D = \pm 0.05$ (at OD=1.2)
			Req - Ruby - 05 - 14	Accuracy of built-in densitometer	Built-in densitometer with calibration function is equipped. $\Delta D = \pm 0.02$ or less (Fog \leq OD < 3.0) $\Delta D = \pm 0.05$ or less (3.0 \leq OD \leq 3.6)
			Req - Ruby - 05 - 15	Gradation processing	Configuration is set to change BAR processing to SAR processing, and vice versa according to each AE-title.
			Req - Ruby - 05 - 16	Interpolated scaling processing	Configuration is set to change SSM processing to A-VR processing, and vice versa according to each AE-title.
			Req - Ruby - 05 - 17	Image format	30 types of standard image formats (1 to 80 frames) and 10 types of mixed image formats are output. Details on the formats are stipulated in DICOM Conformance Statement.
			Req - Ruby - 06	Approx. 80 to 100 sheets of 14"x 17" films can be processed per hour.	Req - Ruby - 06 - 01
		Req - Ruby - 07	Convenient maneuverability like a short starting time is inherited from DRYPIX7000.	Req - Ruby - 07 - 01	Initial output time of film 75 to 85 seconds Films are released at high speed of 100mm/s or more (same as DRYPIX7000) .

Specifications of Ruby

Classification	Customer Requirement Specification & Other Requirements		Design Input		Product Specifications (See main text for details)
	CRS No.	Requirements	Design Input No.	Items	
			Req - Ruby - 07 - 02	Starting time	Cold Start 10 to 15 min. (at 25°C, 12 min. is a target value in design) Hot Start 3 to 5 min. Energy efficient power down mode: 7 to 10 min. Energy efficient sleep mode: 10 to 15 min.
	Req - Ruby - 08	Films (e.g. DI-HL,DI-HLC) used for the conventional DRYPIX7000 is applicable to this System.	Req - Ruby - 08 - 01	Types of films	DI-HL and DI-HLC are used. Service personnel sets a film type (blue or clear), when this System is installed. Bar code reader of the film loading unit identifies the film type, lot, and the like from the bar code label when films are set to the unit (same as DRYPIX7000). Bar code information is printed in any remaining areas other than the effective image recordable area of a film.
	Req - Ruby - 09	Any films among 14"x17"film, 14"x14"film, 10"x14"film, 10"x12"film, and 8"x10"film is selectable.	Req - Ruby - 09 - 01	Sizes of films	14"x 17" (100 sheets per box), 14"x 14" (100 sheets per box), 10"x 14" (150 sheets per box), 8"x 10" (150 sheets per box), 10"x 12" (150 sheets per box) Films specified in size via modality are printed out. Function that a film size is changeable according to each AE-title is equipped. If a film size is changeable, the System will print the available films larger than the originally designated ones first, and then in reducing order.
3. Requirements related to Interface	Req - Ruby - 10	Connectability to FCR is comparable to DRYPIX7000.	Req - Ruby - 10 - 01	Connectable devices	The System is connected to a variety of diagnostic imaging systems corresponding to DICOM Printing. A diagnostic imaging system of non-correspondent to any networks can be connected via DrypixLink. A diagnostic imaging system corresponding to E-DMS/Toshiba Protocol is connected via FN-PS551+DrypixLink.
			Req - Ruby - 10 - 02	Corresponding DICOM service	Images for medical use are printed out corresponding to the following DICOM Print SOP Classes: Verification SOP Class Basic Gray Scale Print Management Meta SOP Class Print Job SOP Class, Basic Annotation SOP Class Queue Management SOP Class, User Preference LUT SOP Class (See DICOM Conformance Statement for more detailed specifications in each Service Class.)
			Req - Ruby - 10 - 03	Number of Associations connected to simultaneously	1~10 (Variable corresponding to configuration setting)
			Req - Ruby - 10 - 04	1セッション内の許容フィルムボックス数	32
			Req - Ruby - 10 - 05	最大入力画像サイズ	8800Rows × 8800 Columns
			Req - Ruby - 10 - 06	画像スプール	受信した画像データはプリント処理が完了するまでHDDにスプールする。未プリント画像のスプール容量は合計3GB。プリント処理が完了したデータで、リプリント候補の画像は合計 6 GB容量までスプール可能。
4 . ヒューマンフ	Req - Ruby - 11	操作性と視認性が当社従来製品DRYPIX 7000と同等以上であること。	Req - Ruby - 11 - 01	排出フィルム取出し性	DRYPIX7000同様、3方向 (正面、右側面、背面) からフィルムの取り出し可能。 本体排出部は 1 5 0 枚集積でも取り出し性を損なわないよう、ソータビンとの間隔を広くする。 ソータ排出部は 3 0 枚集積でも取り出し性を損なわないビン間隔とする。
			Req - Ruby - 11 - 02	フィルム装填性	DRYPIX7000と同じ銀ボリ引き抜き方式
			Req - Ruby - 11 - 03	電源のON/OFF	電源On/Offには以下の手段を持つ。 On : 操作パネルのパワーオンスイッチ、外部装置からのWake On LAN Off : 操作パネルの液晶画面でシャットダウンボタン、主電源スイッチ
			Req - Ruby - 11 - 04	各国語対応	15ヶ国語に対応すること。 日本語、中国語、韓国語 MDD要求の12ヶ国語 英語、仏語、独語、イタリア語、ポルトガル語、スペイン語、ギリシア語、デンマーク語、フィンランド語、スウェーデン語、オランダ語、ノルウェー語 各国語はM-UtyまたはPC-U t y から切替可能とする。 出荷時は英語または日本語の設定とする。
			Req - Ruby - 11 - 05	本体パネル操作性/視認性	4.7インチタッチパネルに装置の状態 (使用フィルムサブライ状態、残フィルム枚数、動作状況、Job状態等) を表示する。 指での操作が無理なく行えるような画面構成/パーツとする (P D A 的なベン操作は前提としない) 。 人間工学的に配慮されたパネル角度
			Req - Ruby - 11 - 06		装置の前に立った場合に視認し易い角度に操作パネル角度を設定する。 離れたところからでもDRYPIX7000同等の視認性を確保する。 シグナルランプを設け、緑、黄、橙で装置状態を表示する。
			Req - Ruby - 11 - 07	ユーザ保守	通常時 : フィルム補給 (フィルム切れの際に実施) 、濃度補正 (必要に応じて実施) 、クリーニングローラの清掃 (必要に応じて実施) フィルム補給/クリーニングローラの清掃のユーザ操作手順は操作パネルに複数画像を連続表示することで説明する。 濃度補正は操作パネルから指示操作を順次行うことで実行可能な手順にする。

Specifications of Ruby

Classification	Customer Requirement Specification & Other Requirements		Design Input		Product Specifications (See main text for details)
	CRS No.	Requirements	Design Input No.	Items	
			Req - Ruby - 11 - 08		異常時：JAM発生時はユーザがカバーを開けてジャムフィルムを取り出す。ジャムフィルムを除去した後、カバー閉にて処理が再開する。その他のレベル1エラーでは、発生要因を取り除いた後のカバー閉により処理が再開する。ユーザ操作手順は操作パネルに複数画像を連続表示することで説明する。レベル0エラー時はエラー発生を知らせるメッセージとエラーコードを表示する。フィルムサプライ/濃度測定機能/ソータが故障しても、それ以外の部分で限定的にプリント処理が実行できる場合は、プリントを続行する。
	Req - Ruby - 12	ユーザーの作業環境に悪影響を与えないこと。	Req - Ruby - 12 - 01	騒音条件	動作時45～50dB、スタンバイ時40～45dB(単発音は除く)。
5. ラベリングと	Req - Ruby - 13	分かりやすいマニュアルであること	Req - Ruby - 12 - 02	有害気体	アンモニア/25ppm以下、二酸化硫黄/2ppm以下、酢酸/10ppm以下、オゾン/0.1ppm以下、ホルムアルデヒド/0.5ppm以下
			Req - Ruby - 13 - 01	取扱説明書	操作手順を正しく、わかり易く記載。
			Req - Ruby - 13 - 02	サービスマニュアル	メンテナンスの手順を正確にわかり易く記載。
			Req - Ruby - 13 - 03	カタログ	装置の持つ主な仕様を記載。
			Req - Ruby - 13 - 04	添付文書	業務に従い、規定の内容を記載。
			Req - Ruby - 13 - 05	定格銘板	業務、UL、TUVに従い、規定の内容を記載。
			Req - Ruby - 13 - 06	注意銘板	各国語に対応。
Req - Ruby - 13 - 07	DICOM Conformance Statement	DICOM通信実装仕様を記載			
	Req - Ruby - 14	梱包が適切であること	Req - Ruby - 14 - 01	梱包	国内：パレット固定+帯電防止袋包装 海外：パレット固定+木枠+防湿袋
			Req - Ruby - 14 - 02	保管環境	温度 -10℃～50℃(結氷なきこと) 湿度 10%～90%RH(結露なきこと) 気圧 500～1060hPa
6. 法規制	Req - Ruby - 15	医療の法規制に適合していること	Req - Ruby - 15 - 01	国内 薬事	安全：JIS T0601-1(1999) EMC：JIS T0601-1-2(2002)
			Req - Ruby - 15 - 02	米国 FDA Medical Device: 21CFR Part 807	安全：IEC60601-1(1988+Am1+Am2) EMC：IEC60601-1-2(2001)
			Req - Ruby - 15 - 03	米国 HHS Light-emitting Products Laser notice 50	IEC60825-1(2001)
			Req - Ruby - 15 - 04	欧州 MDD 93/42/EEC, Medical Device Directive	安全：EN60601-1(1990 +Am1+Am2+Am13) EN60825-1(2001) EMC：EN60601-1-2(2001)
			Req - Ruby - 15 - 05	カナダ MDR (Medical Device Regulations)	安全：IEC60601-1(1988+Am1+Am2) EMC：IEC60601-1-2(2001)
			Req - Ruby - 15 - 06	豪州、中国、台湾、韓国の法規制対応	豪州、中国、台湾、韓国の法規制に対応
7. Acquisition of license for certification	Req - Ruby - 16	To obtain a license for certification conducted by a certification body who gives written assurance that a medical device, process or service conforms to the specified requirements prescribed in the relevant medical device standards.	Req - Ruby - 16 - 01	UL	UL60601-1(2003)
			Req - Ruby - 16 - 02	TUV	EN60601-1(1990 +Am1+Am2+Am13)
8. 安全要求事項 (6と7と10に含む)					
9. 電磁妨害 (EMI) (6と10に含む)					
10. その他の適用	Req - Ruby - 17	医療機器の品質基準に適合していること。	Req - Ruby - 17 - 01	品質に関する社内基準	富士フィルム医療機器品質基準 (K12N0097A) 適合
11. 毒性、生体適合性	Req - Ruby - 18		Req - Ruby - 17 - 02		機器安全設計ガイド Z12S0039, Z12S0042～45, Z12S0057～Z12S0071に準拠
			Req - Ruby - 18 - 01	毒性	適用外
			Req - Ruby - 18 - 02	生体親和性	適用外
12. 滅菌	Req - Ruby - 19		Req - Ruby - 19 - 01	滅菌	適用外
13. 過去の類似した設計から得られた情報	Req - Ruby - 20		Req - Ruby - 20 - 01	顧客苦情・既存機種からの情報	DRYPIX7000等の従来機種の情報を反映

Specifications of Ruby

Classification	Customer Requirement Specification & Other Requirements		Design Input		Product Specifications (See main text for details)
	CRS No.	Requirements	Design Input No.	Items	
14. リスクマネジメント関連	Req - Ruby - 21		Req - Ruby - 21 - 01	リスク分析の社内基準	リスクマネジメント実施要領 (K14N0234)
15. 生産能力/製造工程関連	Req - Ruby - 22	販売目標台数7500台/3年を想定した生産ができること。	Req - Ruby - 22 - 01	製造適性	販売目標台数7500台/3年、FIT/FC製造を想定した設計とする。
			Req - Ruby - 22 - 02	製造設備	販売目標台数7500台/3年を想定した製造設備とする。
16. 輸送/設置条	Req - Ruby - 23		Req - Ruby - 23 - 01	設置に必要な治工具	サービス用標準工具、PC
			Req - Ruby - 23 - 02	設置衝撃規格	富士フィルム医療機器品質基準 (K12N0097A) No.03-03-02
			Req - Ruby - 23 - 03	輸送振動試験	富士フィルム医療機器品質基準 (K12N0097A) No.03-02-03
			Req - Ruby - 23 - 04	輸送衝撃規格	富士フィルム医療機器品質基準 (K12N0097A) No.03-03-04
			Req - Ruby - 23 - 05	設置スペース	下記装置周囲の空間でユーザメンテナンス可能。 前面800mm以上、背面：20mm以上、左面：50mm以上、右面：200mm以上 ※背面は壁にドン付け可能 (背面突起により排気スペース20mm確保)
			Req - Ruby - 23 - 06	設置工数	開梱～画像出力まで1H～3H (接続先の機器設定時間は含まない)
			Req - Ruby - 24 - 01	メンテナンス適性があること。	Req - Ruby - 24 - 01
17. 修理 / メンテナンス関連	Req - Ruby - 24		Req - Ruby - 24 - 02	メンテナンスに必要な治工具	サービス用標準工具、PC、USBメモリ
			Req - Ruby - 24 - 03	メンテナンス時の交換単位	故障時のパーツ交換は、単品あるいはアッシー交換可能
			Req - Ruby - 24 - 04	定期メンテナンス項目	1年未満の定期メンテナンス不要
			Req - Ruby - 24 - 05	メンテナンス機能	本体パネルから通常のメンテナンス可能 設置や異常時解析作業においてはサービスPCを使用 ハードウェア各ユニットのチェック機能、システム設定管理機能、濃度補正機能、フィルム出力機能を持つ。 装置の動作Logを記録し、メンテナンス機能にて装置外へ取り出し解析に使用する。
			Req - Ruby - 24 - 06	ケーブル接続	□電源ケーブルインレット、LANケーブルコネクタは装置背面に配置。 □電源ケーブル、LANケーブルは装置に固定可能とする。
18. 付属品/補助用具との適合性	Req - Ruby - 25		Req - Ruby - 25 - 01	付属品の適合性	増設枚葉装填部/ソータ/メモリのオプションを持つ (市場増設可) 。 車載仕様オプションを設定する。
19. 環境関連の社内基準	Req - Ruby - 26		Req - Ruby - 26 - 01	環境配慮設計	機器環境配慮設計実施要領 (K14N0231) 準拠
			Req - Ruby - 26 - 02	LCA対応	機器LCA計算要領 (14N0233) 準拠。LCAはDRYPIX7000同等以下。
			Req - Ruby - 26 - 03	省エネ対応	省エネ、スタンバイモードを持つ。待機状態での消費電力はDRYPIX7000同等以下。 省エネ、スタンバイモードへは、カレンダータイマ設定と一定時間アイドル状態を経過した後、移行する。
20. 臨床評価	Req - Ruby - 27		Req - Ruby - 27 - 01	臨床評価	臨床評価要領 (K14N0235B) 準拠。
21. コスト	Req - Ruby - 28	販売目標台数7500台/3年を想定して、ミッドレンジとして競争力のある価格帯を実現すること。	Req - Ruby - 28 - 01	製造コスト	コストは別紙参照。
			コンポーネントへの要求仕様		

[*Ruby Specifications: Supplement*]

■ Design & Architecture

□ External View



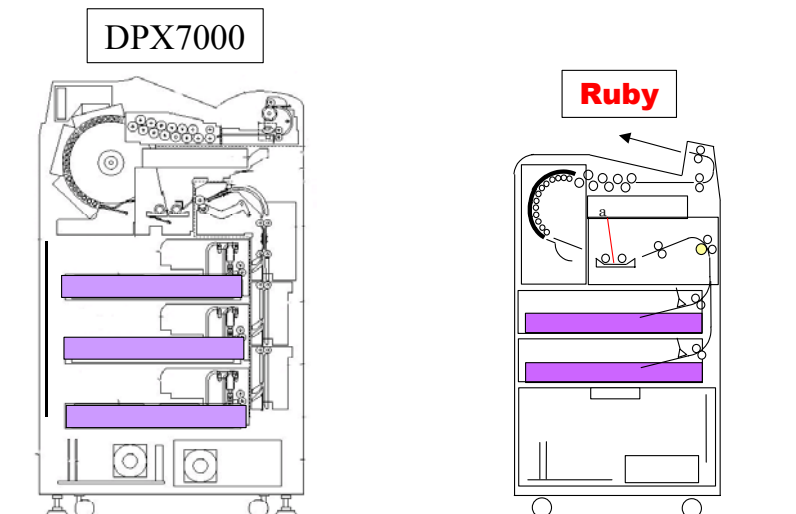
Sorter (Optional) attached



Oblique rear view



Panel



Architectural Comparison between Ruby and DRYPIX 7000

- The recording synchronous heat development system is employed with the specified conveyance layout in a same manner as DRYPIX 7000.
- Up to two (2) trays can be mounted for future additions.
- Released films can be accessed from all directions (from three directions except the right hand side, when a sorter is attached).
- Jammed films are removed from the front, top or right side face.
- Control boards and power supply system shall be placed collectively to the lower part of this System.
- Optional sorter can be attached to the upper part of this System.
- Combination of adding parts and mounting a vibration proof platform can give to harmonize with the required conditions when loading this System on a mobile.

■ Indication for Use

Ruby is indicated for use in providing diagnostic quality medical images on film for aid in physician diagnosis, including the printing of images and associated identification information from various digital imaging source modalities, including but not limited to, Computed Tomography (CT), Magnetic Resonance Imaging (MRI), Ultrasound, Computed Radiography, Digital Radiography, Digital Mammography and Nuclear Medicine.

**Substantial Equivalence (SE) Feature Comparison
DRYPIX 4000 to DRYPIX 7000 & DRYPIX 5000**

Parameter	Fuji DRYPIX 4000	Fuji DRYPIX 7000	Fuji DRYPIX 5000
Light source/modulation	Laser diode Direct modulation Thermal (dry) developer	Laser diode Direct modulation Thermal (dry) developer	Laser diode Direct modulation Thermal (dry) developer
Throughput	115 films/hr (14"x17") 170 films/hr (10"x14")	180 films/hr (14"x17") 240 films/hr (10"x14") 200 films/hr (8"x10")	130 films/hr (14"x17") 180 films/hr (10"x14") 180 films/hr (8"x10")
Film type	Fuji dry imaging film DI-HL (blue base), DI-HLc (clear base)	Fuji dry imaging film DI-HL (blue base), DI-HLc (clear base)	Fuji dry imaging film DI-HL (blue base), DI-HLc (clear base)
Film size	14"x17", 14"x14", 10"x14", 10"x12", 8"x10"	14"x17", 10"x14", 8"x10"	14"x17", 10"x14", 8"x10"
Film holding capacity	150 sheets + 150 sheets (2 nd film tray optional)	100 sheets + 100 sheets (2 nd , 3 rd film trays optional)	100 sheets + 100 sheets (2 nd , 3 rd film trays optional)
Film loading	Daylight loading (no magazine)	Daylight loading (no magazine)	Daylight loading (no magazine)
Sorter	Yes (optional)	Yes (optional)	Yes (optional)
Sampling raster	100 µm x 100 µm 50 µm x 50 µm	100 µm x 100 µm 50 µm x 50 µm	100 µm x 100 µm 50 µm x 50 µm
Rasters of main and auxiliary sampling	10 pixels/mm 20 pixels/mm (50 µm mode)	10 pixels/mm 20 pixels/mm (50 µm mode)	10 pixels/mm 20 pixels/mm (50 µm mode)
Maximum number of recording pixels	3520 x 4280 5080 x 7200 (50 µm mode)	3520 x 4280 5080 x 7200 (50 µm mode)	3520 x 4280 5080 x 7200 (50 µm mode)
Time to output 1 st film	80 sec	65 sec	65 sec
Effective Gray Scale	14 bits	14 bits	14 bits
Maximum Density (Dmax)	3.0 to 3.6 (configurable)	3.0 to 3.6 (configurable)	3.0 to 3.6 (configurable)
Film density control	Yes (Auto)	Yes (Auto)	Yes (Auto)
Gradation curve variability	8 independent types selectable	8 independent types selectable	8 independent types selectable
Negative/positive selection	Yes	Yes	Yes
Black/clear border changeover	Yes	Yes	Yes
Format	1, 2, 3, 4, 6, 8, 9, 12, 15, 16, 20, 24 or mixed 4, 25, 30, 35, 36,42, 48, 49, 54, 56, 60, 63, 64	1, 2, 3, 4, 6, 8, 9, 12, 15, 16, 20, 24 or mixed 4, 25, 30, 35, 36,42, 48, 49, 54, 56, 60, 63, 64	1, 2, 3, 4, 6, 8, 9, 12, 15, 16, 20, 24 or mixed 4, 25, 30, 35, 36,42, 48, 49, 54, 56, 60, 63, 64
DICOM capability	Yes	Yes	Yes
Size ("w" x "d" x "h")	630mm x 600mm x 1100mm	735mm x 680mm x 1240mm	735mm x 680mm x 1240mm
Weight	150 kg (330 lbs)	200 kg (440 lbs)	203 kg (448 lbs)
Power	100-120 Vac, 12A, 50/60Hz 200 to 240 Vac, 7A, 50/60Hz	200/220/230/240 Vac, 11/10/9.5/9A, 50/60Hz	100/110/120 Vac, 12A 50/60Hz