

Digital Dental Primer

Your Guide to Successful Implementation
of
Digital Dental Radiography



AF Clinical Engineering

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List of Terms

Acronyms/Definitions:

CCD: Charge Coupled Device

CMOS: Complementary Metal Oxide Semiconductor:

PSP: Photostimulable Phosphor Plates: Similar in size to conventional film, after exposure, the phosphor plate is placed in a scanner that converts the image stored on the plate to digital format. Considered an indirect system.

MAJCOM: Major Command

MILCON: Military Construction

PACS: Picture Archiving and Communication System

CIO: Chief Information Officer

DCO: Dental Care Optimization

BMET: Biomedical Equipment Technician

IT: Information Technology

ICTO: Interim Certificate to Operate

IATO: Interim Authority to Operate

CON: Certificate of Networkiness

SSAA: System Security Authorization Agreement

FINPLAN: Financial Plan

MEMO: Medical Equipment Management Office

DSCP: Defense Supply Center Philadelphia

FDA: Food and Drug Administration

EPA: Environmental Protection Agency

Direct Digital System: Acquire images with a solid-state sensor that is connected to a computer to produce a digital image

Indirect Systems: Requires some type of conversion to digital format using a converter box, phosphor plate scanner, etc. Time lag between exposure and image acquisition exists.

Solid-state sensor: Used for direct digital capture of dental radiographic images

Converter Box: Converts an analog image to a digital image.

Spatial Resolution: Number of pixels horizontally and vertically in a digital image, i.e. 640 x 480, 800 x 600

Contrast Ratio: The ratio of the brightest and darkest images a display can reproduce

Pre-purchase process:

1. Planning participants: It is imperative that the following individuals or offices be part of the planning process from inception of equipment requirements. Please see the Roles and Responsibilities attachment for further details on personnel involvement.

Site Level:

- Dental Flight CC
- Medical Logistics Officer/NCO
- Senior Biomedical Equipment Technician
- Facility Manager
- Hospital IT
- Base COMM
- MEMO

MAJCOM Level:

- MAJCOM Logistics
- MAJCOM Dental Rep
- MAJCOM CIO

2. Be prepared with the following information for your meeting:

- Copy of Dental Care Optimization Plan
- Current equipment inventory – most importantly the age of current x-ray equipment
- Standard equipment formula ([hyperlink this](#))
- Current digital equipment throughout the MAJCOM
- Requirements for network certification (IT folks will have this information)
- Current funding status (local or central)
- Any existing due-ins for dental x-ray equipment
- MILCON planned for your facility?

3. The first meeting should prepare your facility for the digital dental initiative. The following should be determined:

- Is your clinic ready for digital dental?
- Your anticipated date for Dental Care Optimization
- The project POC
- Who will be your dental PACS administrator (Suggest IT and BMET with full rights)
- Internal timeline for deployment of digital dental
- Who is the POC for ensuring Network Certification?
- What is the timeframe for obtaining an interim certificate to operate (ICTO)
- Will you be a regional hub for image storage?
- Can the equipment be sustained/maintained by local BMETS?

4. At the second meeting you should discuss:

- Final configuration for your site (Use the Digital Dental Configuration sheet)
- Prep for vendor visit – determine best dates and time
- IT timeline for ICTO

5. Planning for the site visit: The following individuals should be present for the vendor site visit. Make sure to coordinate the visit so all personnel can attend:

- Dental Flight CC
- Medical Logistics Officer/NCO
- Senior Biomedical Equipment Technician
- Facility Manager
- Hospital IT
- Base COMM

The following should be completed prior to the vendor site visit:

- Configuration Worksheet

6. The following should be provided to you by the vendor:

- Vendor generated final configuration: this configuration should match your internally developed configuration with minor adjustments
- Quote for the final configuration

7. Now that you have completed the site visit, it is time to prepare your acquisition documents. The acquisition documents will be based on the vendor quote. Use the attached templates to complete your equipment package (see the attached checklist for all required documents). The completed package must be routed/signed and follow the distribution/review chain outlined in the attached flowchart. Follow the appropriate chain for local or central funding. No packages will be accepted without the complete review. The cover sheet must be signed by all reviewers.

8. In conjunction with acquisition document completion/routing, you should begin the Network Certification process. Attached you will find the signed AETC Authority to Operate (ICTO) letter. This will be an important document for obtaining an Interim Certificate/Authority to Operate followed by the Certificate/Authority to Operate. An ICTO must be in-hand prior to connecting your digital equipment to your hospital network. Follow the attached guidelines for starting the certification process. These guidelines are just the first steps and must be used in conjunction with certification requirements for your respective MAJCOM. Your IT personnel and Base COMM should be the POCs for obtaining your network certification.

Site Prep:

1. Now that you have submitted your approved/signed acquisition documents, you must prepare your site for the installation of your digital dental equipment. All facility modifications and network security requirements should already be identified on the Attachment 27 and Site Prep Requirements checklist. Complete all prep requirements identified on these documents. Attached you will find general site prep requirements provided by the integrator. The culmination of following your site prep requirements list, Attachment 27, and integrator site prep list will be a facility totally ready for the installation of digital dental equipment. It is vital that you start your facility prep early. If facility mods are required, it is the sites responsibility to request their own funds for the facility mods. If funding is not available and modifications are required, do not submit your package.

Installation:

1. During installation, the following personnel are integral to a successful integration:

- Dental POC
- BMET
- Facility Manager
- IT

2. The actual duration of your on-site installation will vary depending on your specific equipment configuration. Various manufacturers will be installing your equipment. The exact vendor list will vary depending on the specific equipment configuration for your site. You can expect the following vendors:

- Force3
- Planmeca
- Schick

3. During the install, your integrator will be your liaison for all of the vendors. They will coordinate with the various manufacturers to ensure a seamless transition.

Training:

1. Training will be provided on-site by each manufacturer and coordinated by the integrator. Training will include user, administrator, and maintenance training. User, administrator, and maintenance service manuals (two copies) will be provided to each facility. It is imperative that you know who will be attending the training sessions prior to the vendors arriving at your location. At a minimum, two dental technicians, two hospital IT personnel, and two Biomedical Equipment Maintenance Technicians should be in attendance. Future training will be the responsibility of the local facility.

Post-installation support (1st year):

Post-installation support will be provided by specific manufacturers via Force3. Force3 will continue to act as the integrator for a period of one year after the date of equipment acceptance. Force3 acts as the one stop shop for your technical and maintenance support issues. An 800 number will be provided to you by Force3. Call this number for any technical or maintenance issues and Force3 will coordinate with the appropriate vendor, i.e. MEDICOR for software issues, Planmeca for pano unit issues, Schick for sensor issues.

Software updates: software updates will be provided by each manufacturer at no additional cost for the first year after system acceptance. Any updates past the initial warranty year will be at the cost of the local facility. It is imperative that you budget for these out-year updates.

Out-year maintenance:

Out-year maintenance, support, and software update/license renewal are all costs borne by the local facility. It is imperative that you make decisions regarding the aforementioned now to allow time for addition to your FINPLAN. Various contract mechanisms will be available to you at the local and central level, but it is highly recommended that you maintain your equipment in-house through local BMETs and IT personnel. Training is provided on site to alleviate the learning curve with your new equipment.

Digital Dental-Roles and Responsibilities

Rolls and Responsibilities:

Below you will find the roles and responsibilities for the major players in the digital dental radiography implementation. Communication is absolutely critical to the success of the implementation. The information below is not all inclusive but covers the basic role each person/office plays in the process.

Dental Flight CC: Primary coordinator for the initiative. Should coordinate initial meetings and should determine final requirements for the dental clinic. Should be knowledgeable on the DCO timeline for your specific base and should shape the final configuration based on clinical requirements.

Dental Technicians/Dental Supply Custodian: Provide valuable input on the throughput/patient flow of the dental clinic, supply requirements, etc. Provide valuable information on product capabilities, research skills, and supply requirements for new equipment.

Medical Logistics: Absolutely integral part of the initiative. A major coordinator of the acquisition and installation process. Will coordinate with the MEMO, BMETs, and Facility Management

Biomedical Equipment Technicians: Imperative to effective installation. Will be the primary office to review technical requirements for modalities, installation requirements, maintenance requirements, and overall sustainment issues. Should be consulted on all maintenance related issues and should work the Attachment 27 in conjunction with Facility Management and IT. Should be a PACS administrator.

Facility Manager: Critical to effective installation. Will provide infrastructure review (HVAC, plumbing, walls, electrical requirements, coordinate lead shielding survey with the BEEs) for the digital dental solution. Coordinates any structural renovation requirements through CE, manufacturer, etc. Should be consulted on all facility management related issues. Should work the Attachment 27 in conjunction with the BMETs and IT.

Hospital IT: Should be the primary POC for network certification requirements. Should be knowledgeable of all LAN drop requirements and should be a PACS administrator. Should work closely with Base COMM to ensure all installation IT requirements are met. Should work the Attachment 27 with the BMETs and facility Management.

Base COMM: Should be a consultant to the Hospital IT shop. Should provide all installation COMM requirements and act as QC for Hospital IT

MEMO: Should provide acquisition expertise. Must be knowledgeable of gain procedures and work closely with the BMETs to ensure the proper device codes, manufacturer, model, serial #, and maintenance plans for new equipment. Vital to device alert distribution, proper maintenance performed (extremely important during warranty year).

Digital Dental Configuration Sheet

The following guidelines will help you determine the digital dental configuration for your facility. This is the text version of the guidelines. Attached is the Excel spreadsheet that you will use to enter your specific facility information.

1. Technology Solution:
 - a. Deploy mixed solution that meets your clinical needs
 - b. Can include a combination of solid state sensors and phosphor plate (PSP) technologies
2. Panoramic/Ceph X-ray:
 - a. Consider direct digital for new acquisition
 - b. Retrofit panoramic units less than 5 years old with PSP solution
 - c. Approved list of Panoramic X-ray machines. All machines are approved for use, but the Planmeca is the recommended standard medical device:
 - i. Planmeca Digital Promax:
 - ii. Kodak 8000C
 - iii. Schick DCRPanX
 - d. Approved PSP:
 - i. Air Techniques ScanX Digital Imaging System
 - e. If you choose to implement PSP technology at your facility, you must give up two #2 sensors per standard configuration
3. Intraoral Sensors:
 - a. Approved manufacturer list. Schick is the recommended standard sensor:
 - i. Schick
 - ii. Kodak
 - b. Sensor deployment ratios:
 - i. Deploy one size #2 digital sensor per tubehead under the Dental Care Optimization plan
 - ii. Size #1 sensors: Deploy $\frac{1}{2}$ the number of #2 sensors
4. Printer solution:
 - a. Ink-jet printer solution is approved and recommended for total digital solution.
5. Workstations:
 - a. Workstations are recommended if you do not currently have the supporting IT infrastructure
 - i. Monitors: 400 to 1 contrast ratio, consider monitors in speakers, 17" at a minimum
 1. Consider mounting arms if tabletop mounting is not an option
 - ii. CPU: Consider space when choosing CPU configuration...full size towers may take up too much space.

Digital Dental Configuration Worksheet

The following worksheet will calculate your digital dental solution based on your inputs. Only fill in the yellow highlighted areas below. The rest of the fields will calculate automatically to give you a final approximate solution cost. This worksheet should be completed prior to requesting/receiving a quote from an integrator. Use the approximate cost from this sheet as a basis of comparison for your actual quote. This worksheet is for planning purposes only and is not considered a quote.

Base:

Modality	Criteria	Quantity	Pano Requirement	Approximate Cost	Total Cost
1. Panoramix X-Ray:	Number of Pano units less than five years old being considered for conversion	0			
	Number of Pano units greater than five years old being considered for replacement	0			
	Retrofit with Phosphor Plate Technology (PSP)	0	0	Cost listed below in PSP section	
	Purchase new direct digital	0	0	\$35,000	\$0
	Will you be requesting Pan/Ceph capabilities with your direct digital unit?				\$0
		Total Requirement	0	Total Pano Cost	\$0

Modality	Criteria	Quantity	PSP Requirement	Approximate Cost	Total Cost
2. PSP	Pano unit being converted is less than five years old	0	0	\$20,000	\$0
	We do not have a Pano unit less than five years old, but are willing to give up 2 #2 sensors for PSP (includes start-up supply costs...Enter quantity requested to the right)	0	0	\$20,000	\$0
		Total Requirement	0	Total PSP Cost	\$0

Modality	Criteria	Quantity	Sensor Requirement	Approximate Cost	Total Cost
3. Sensors	Number of current tubeheads	0			
	Number of additional tubeheads proposed under DCO plan	0			
	#2 size sensors (1 per DTR)	0	0	\$5,000	\$0
	#1 size sensors (1/2 the number of #2 sensors)	0	0	\$4,300	\$0
	CDR USB Remote	0	0	\$1,000	\$0
					Subtotal
	Sensor adjustment if PSP replacement is approved				\$0
		Total Requirement	0	New Total	\$0

Modality	Criteria	Quantity	PACS Requirement	Approximate Cost	Total Cost
4. PACS (Includes MEDICOR software)	Standard PACS Server Solution	1	1	\$0	\$0
	Will you be a regional archive site(If unsure, enter NO?)				
	Regional Archive Adjustment		0	\$30,000	\$0
	MEDICOR Software (site licenses)	0	0	\$410	\$0
		Total Requirement	1	Total PACS Cost	\$0

Modality	Criteria	Quantity	Printer Requirement	Approximate Cost	Total Cost
5. Printer Solution	Generic Ink-jet printers are default for digital dental solutions. If you are requesting a high-end Codonics printer it will have to be approved through the AFDenT				
	Ink-jet Printer	1	1	\$299	\$299
	Will you be requesting a Codonics printer?				
	Codonics printer adjustment	0	0	\$18,000	\$0
		Total Requirement	1	Total Printer Cost	\$299

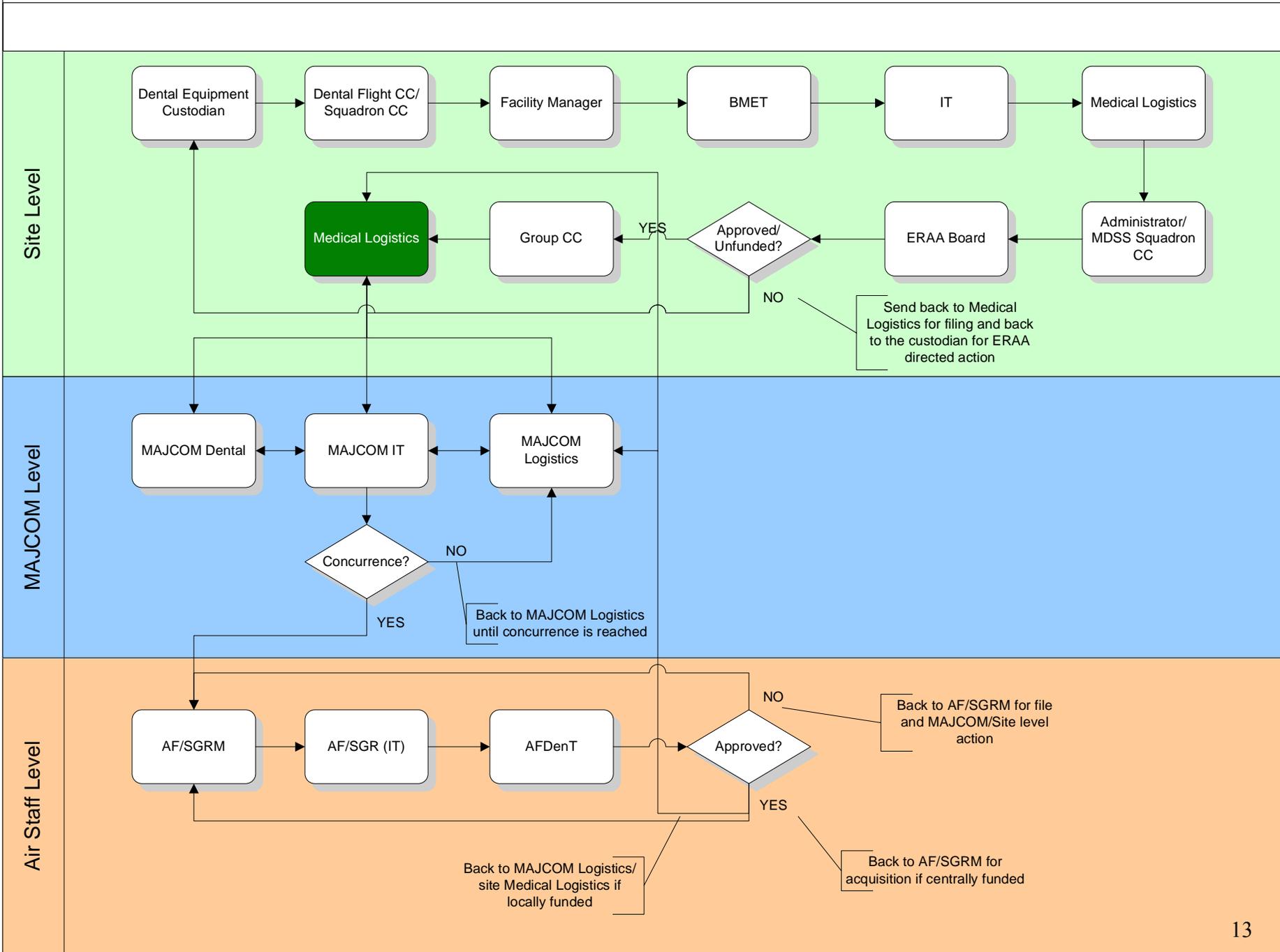
Modality	Criteria	Quantity	W/S Requirement	Approximate Cost	Total Cost
6. Workstations	Workstations are recommended if you do not currently have the supporting IT infrastructure (does not include monitor cost)	0	0	\$1,200	\$0
		Total Requirement	0	Total W/S Cost	\$0

Modality	Criteria	Quantity	Flat Panel Req	Approximate Cost	Total Cost
7. Flat Panel Monitors	Space constraints in DTRs necessitate flat panel monitors...monitors will be at a minimum 17" with at least a 400:1 contrast ratio.	0	0	\$400	\$0
		Total Requirement	0	Total Monitor Cost	

Modality	Criteria	Quantity	Tube Head Req	Approximate Cost	Total Cost
8. Tube Heads	Imperative to decide on correct location for mounting the tubeheads. Enter the number of tubeheads to the right	0	0	\$2,800	\$0
			Total Requirement	0	Total Tube Head Cost

Total Solution Cost	\$299
Intallation/Training	\$30
Total Approx Cost	\$329

Digital Dental Equipment Request Routing Process



GUIDELINES FOR COMPLETION OF DIGITAL DENTAL XRAY 601s

Complete the AF Form 601 according to standard guidance with the following exceptions:

1. **Block 13:** Put the total price quote in this block. You will break out modality/PACS solution costs on the breakout attachment. Rationale: The single quote is being provided by an integrator. They have included modalities as part of the entire digital solution, but each modality will be indexed separately. The PACS solution will be coded separately as a system, with all parts listed as components. As a result, we must breakout the costs on the 601.
2. **601 Breakout Attachment:** Complete the spreadsheet.
 - a. **MODALITIES:** Each modality must be listed on the breakout. If you are ordering a Planmeca Pano and a Schick Intraoral X-ray sensor, you will have two modality line items. If you order two Planmeca Panos (same model) and a Schick Intraoral X-ray sensor, you will still have two line items, with a quantity of two for the pano machines. The cost for each modality will include the equipment price, its accessories (sensors, etc.) and the install charges. Nutshell: each type of sensor, psp imaging system, or digital modality must be a separate line item.
 - b. **PACS:** The PACS solution will basically include everything else on the quote to include install charges, first year maintenance, printers, IT software/hardware/licenses.
 - c. **TOTAL COST:** modality cost plus the PACS cost should mirror the amount listed in Block 13 of the AF Form 601.

Digital Dental Acquisition Document Checklist

Follow this checklist to ensure all document requirements are met for your digital dental solution:

Document	Completed
601 Coversheet	<input type="checkbox"/>
AF Form 601	<input type="checkbox"/>
601 Breakout Attachment	<input type="checkbox"/>
13 Point Justification	<input type="checkbox"/>
Attachment 27	<input type="checkbox"/>
Vendor Quote	<input type="checkbox"/>

APPROVED LIST: DIGITAL DENTAL RADIOGRAPHY*

Type	Manufacturer	Model
PACS	MEDICOR	MiPACS
Panoramic/Ceph X-ray	Planmeca	Digital Promax
	Kodak	8000C
	Schick	DCRPanX
PSP	Air Techniques	ScanX Digital Imaging System
Intraoral Sensors	Kodak	RVG 6000
	Schick	CDR Intraoral Sensor and USBCam Digital Intraoral Capture Device

*Based on SSAA for Digital Dental Radiology (DDRS version 1)

Digital Dental Equipment Request Coversheet

All individuals below must review the digital dental equipment request and sign below. No packages will be accepted without all signatures.

Office	Signature	Date
Site Level		
Dental Flight CC		
Medical Logistics Flight CC		
Facility Manager		
Senior BMET		
IT Officer/NCO/Civilian		
MAJCOM Level		
HQ Medical Logistics		
HQ Dental		
HQ IT		
Air Staff Level		
AF/SGRM		
AF/SGD		

Digital Dental Radiography Breakout

Modality Breakout

Panoramic Units	Nomenclature	Qty	Unit Cost	Subtotal Cost
Unit				
Accessories				
Installation				
Subtotal Cost				\$0
Printer Solution	Nomenclature	Qty	Unit Cost	Subtotal Cost
Unit				
Accessories				
Installation				
Subtotal Cost				\$328
Sensor Solution	Nomenclature	Qty	Unit Cost	Subtotal Cost
Unit				
Accessories				
Installation				
Subtotal Cost				\$77,266
Workstations	Nomenclature	Qty	Unit Cost	Subtotal Cost
Configuration				
Accessories				
Installation				
Subtotal Cost				\$0
Software Cost	Nomenclature	Qty	Unit Cost	Subtotal Cost
				\$9,020
PSP	Nomenclature	Qty	Unit Cost	Subtotal Cost
				\$14,683
Wall Mounts	Nomenclature	Qty	Unit Cost	Subtotal Cost
				\$0
Installation/Train/Support/S&H Cost	Nomenclature	Qty	Unit Cost	Subtotal Cost
				\$39,918
PACS Server	Nomenclature	Qty	Unit Cost	Subtotal Cost
Subtotal Cost				\$82,449
Total Cost				\$223,664

13 POINT JUSTIFICATION FOR DIGITAL DENTAL IMAGING EQUIPMENT REQUESTS

- REFERENCE:** (use local MEMO procedures for tracking purposes)

- FUNCTIONAL DESCRIPTION:** Digital Radiography is a computerized imaging system that utilizes an electronic sensor in place of dental x-ray film. The sensor produces a sharp image instantly on the computer monitor without the use of processing chemicals and greater than 90% reduction in radiation exposure to the patient than conventional film x-rays. It enables visualization of teeth and bone clearly with the capability to zoom, colorize, measure, and print the image. It will be used in the dental clinic by specialty sections, general dentistry, and education of residents. All software will be installed in each dental treatment room with access to a server for online storage.

- CURRENT METHOD:** Analog (wet) film processing and manual distribution of images.

- WORKLOAD DATA:** The dental squadron/flight produces and average of _____ radiographs monthly.

- SIMILAR ITEMS:** None. Initiative generated in compliance with guidelines set forth in the AFMS Dental Care Optimization Plan.

- SAVINGS/BENEFITS:** Enterprise wide digital imaging is critical to maximize return on investment of DCO, standardization of dental technology eliminates proprietary software facilitates accurate and timely diagnosis and treatment planning, critical for geographically separated clinics and deployed forces during military and homeland defense contingencies, eliminates chemical film processing and disposal of RCRA hazardous wastes (e.g. Pb, Ag), allows the creation of a web-based electronic repository dental radiographs for all AD and ARC personnel, creates database available for forensic identification and population health studies

- COMPARABLE ITEMS:** Comparable items are reviewed by Dental Evaluation & Consultation Services (DECS) and the Air Force Dental Technology Board (AFDenT).

- OPERATIONAL COSTS:** Local O&M expenditures will be required for replacement imaging plates, system maintenance contract, and travel costs associated with any off-site training provided by the vendor.

- QUALIFIED USERS:** Local facility will designate personnel to be trained. Training will include at a minimum: clinical users and system administration.

- INSTALLATION:** The system vendor will conduct installation; Final acceptance testing will be conducted by in-house Biomedical Equipment Technicians and in-house Information System technicians

- MAINTENANCE SUPPORT:** In-house biomedical equipment personnel can provide maintenance support for all modalities. Server solution will be covered via contractor maintenance support for the initial year. Out-year maintenance support is a local facility O&M budget requirement.

- HISTORICAL MAINTENANCE REPORT:** N/A

HIGH COST MEDICAL/DENTAL EQUIPMENT: This requirement has been deleted

Attachment 27

FORMAT OF SUPPORTING STATEMENTS FOR EQUIPMENT ACQUISITION

PART I - BIOMEDICAL EQUIPMENT MAINTENANCE SECTION

A25.1. Equipment Description (Very briefly describe what the equipment is used for):_

Digital Radiography is a computerized imaging system that utilizes an electronic sensor in place of dental x-ray film. The sensor produces a sharp image instantly on the computer monitor without the use of processing chemicals and greater than 90% reduction in radiation exposure to the patient than conventional film x-rays. It enables visualization of teeth and bone clearly with the capability to zoom, colorize, measure, and print the image. It will be used in the dental clinic by specialty sections, general dentistry, and education of residents. All software will be installed in each dental treatment room with access to a server for online storage.

A25.1.1. Nomenclature (A generic description is preferred. Use brand name only if generic description is not available):

Radiography System, Digital, Dental

A25.2. Is this item a replacement for an existing unit?

- No Yes If No, skip to paragraph **A25.4.**
If Yes, recommend disposition of the existing system.
 Retain as back-up Excess Turn-in to DRMO Other

A25.3. Does the Historical Maintenance Report (HMR) accurately reflect the condition of the existing unit(s)?

- No Yes If No, or if the HMR is not available, comment on the condition of the unit: **N/A**

A25.4. Consider the following technical factors concerning the specific item being requested:

A25.4.1. Electrical Requirements:

Complete list below or check N/A and skip to paragraph A25.4.2.

Voltage (VAC): 110/120 Minimum Regulation Required: ___%

Amperage: Continuous _____ Momentary _____

Hertz: Phases:

Dedicated power line required? No Yes

Conditioned power required? No Yes

Uninterruptible power supply (UPS) required? No Yes

If Yes, has the user requested UPS through appropriate channels? No Yes

Ordered with PACS equipment

If No, do not submit package until UPS has been requested.

Any unusual electrical requirements? No Yes If Yes, explain:

A25.4.2. Plumbing requirements: Complete list below or check (X) N/A and skip to paragraph A25.4.3.

Hot water: No Yes Temp range: _____ - _____ degrees F or C
Cold water: No Yes
Drainage: No Yes _____ Inch pipe
If Yes, does this unit discharge chemical wastes, effluent, sodium acids or other hazardous materials into drainage systems? No Yes
If Yes, has Bioenvironmental Engineering reviewed these discharges in accordance with environmental and health standards? No Yes
If No, do not submit this package until this review is conducted.
If Yes, provide a copy of the Bioenvironmental Engineer's review.
Is the drain for a photographic film processor? No Yes
If Yes, will it be used to process silver-containing films or materials? No Yes
If Yes, is silver recovery equipment available or has it been requested? No Yes
If No, provide for silver recovery before submitting this package.
Steam: No Yes Pressure range ___ - ___ psi
Air: No Yes Pressure range ___ - ___ psi

Oxygen (O2): No Yes
Nitrous oxide: No Yes
Nitrogen: No Yes
Vacuum: No Yes Inches of mercury _____ in. Hg
Any unusual plumbing requirements? No Yes If Yes explain:

**A25.4.3. Heat, Ventilation and Air Conditioning (HVAC) Requirements:
Complete list below or check () N/A and skip to paragraph A25.4.4.**

Temperature range: 15 - 30 degrees C
Humidity range: 15- 75 percent
Air recirculation: _____ Exchanges per hour
Dedicated exhaust/ventilation duct required? No Yes
Does this unit discharge chemical wastes or effluent into ventilation systems or the environment?
 No Yes If Yes, has Bioenvironmental Engineering reviewed the discharges in accordance with health and environmental standards?
 No Yes If No, do not submit this package until this review is conducted.
If Yes, provide a copy of the BEE's review.
Any unusual HVAC requirements? No Yes If Yes explain:

A25.4.4. Structural Requirements: Complete list below or check () N/A and skip to paragraph A25.4.5.

Are doorways/hallways tall enough? () No () Yes () N/A

Are doorways/hallways wide enough? () No () Yes () N/A

Will ceiling support weight? () No () Yes (X) N/A

Will wall support weight? () No () Yes (X) N/A (Yes, if tubehead is part of package)

Will floor support weight? () No (X) Yes () N/A

Does unit generate radiation? (X) No () Yes

If Yes, has the Base Radiation Protection Officer evaluated the existing shielding or the need for new or increased shielding? () No () Yes

If No, do not submit the package until the evaluation is completed.

If Yes, attach a copy of the evaluation.

A25.4.5. Is room lighting adequate for operating and maintaining the equipment?

() No () Yes If no, has the requirement been identified and included in the room modification requirements?

() No () Yes If No, do not submit package until lighting requirements are adequately addressed in the room modification requirements.

Any unusual structural requirements? () No () Yes If Yes, explain:

A25.4.6. Has the Facility Manager submitted an AF Form 332 for the preceding items that require CE support?

() No () Yes If No, Facility Manager must explain in Facility Management Section.

If Yes, date the request was submitted: _____.

A25.4.7. Have the requester and the Facility Manager assessed the communications requirements?

Consider telephones, modems and computer networks data lines, routine and code response pagers, room-to-room intercoms, nurse/patient call systems, etc.

() No. () Yes, but no changes are required. () Yes and changes are required.

If "No," assess communications requirements before submitting this package.

If "Yes, but no changes are required," proceed to paragraph **A25.5**.

If "Yes and changes are required," attach copies of supporting documentation (e.g., AF Form 332, AF Form 601, AF Form 3215).

Does the manufacturer have a process for validating security patches and software upgrades?

() Yes () No

Explain the process:

Does the manufacturer allow qualified local personnel to update/install software upgrades and security patches? () Yes () No
If Yes, [] dial-up, [] direct download, [] firmware update, [] send back to manufacturer, [] other.
If No, Explain how software updates and security patches will be applied.

A25.5. Are there any other manufacturers who can provide the item being requested?

() No (X) Yes If Yes, provide name, address, model number, etc.:

Comparable items are reviewed by Dental Evaluation & Consultation Services prior to vendor selection.

A25.6. Installation: Complete list below or check () N/A and skip to paragraph A25.7.

Who will install unit?

(X) Manufacturer () Requester () BMET () CE () MERC

If Manufacturer, provide estimated cost, if any: \$ _____

Has installation site been selected? () No () Yes

If No, do not submit request until site is selected.

Is a CE project required to prepare the site? () No () Yes

If Yes, the Facility Manager must give site preparation cost estimate in Part II.

A25.7. Maintenance/Repair: Complete list below or check () N/A and go to paragraph A25.11.

Do in-house capabilities exist? (X) No () Yes

If Yes, indicate the number of trained technicians: _____

If No, indicate the reason(s):

(X) Experienced technicians not assigned or are scheduled to depart before the unit is installed.

(X) Test equipment/tools not available. Have steps been taken to acquire necessary test

equipment/tools? () No () Yes If No, explain:

(X) Technicians not trained. Provide source and cost of training if available: (X) 382 TRS

(X) Manufacturer () Other: _____ Estimated cost: \$ _See Quotation_

() Other reasons (Explain):

382 TRS will stand up a course in Dec 2004 with limited availability. 2 BMET training courses are included in the quotation

If in-house maintenance capabilities do not exist and cannot be obtained, suggest a source of maintenance service. () Army Depot: _____

(X) Manufacturer: _____ () Other: _____

If contract support is required, will it be: () Full time (X) As needed () Other (explain):

Provide estimates for annual cost: (Strike out entry which does not apply in any year.)

1st Year Warranty or \$ _See Quotation

2nd Year Warranty or \$ See Quotation

3rd Year Warranty or \$ See Quotation

4th Year Warranty or \$ See Quotation

5th Year Warranty or \$ See Quotation

Coverage provided by servicing contractor: (X) All labor (X) Parts

(X) Travel (X) Emergency response () Preventive maintenance

Provide additional justification of the requirement for contract maintenance. (Note that in-house service is the preferred method to accomplish maintenance.)

A25.8. Technical Literature: Are you requesting at least two (2) copies of all necessary service literature, schematics, theory of operation for all circuitry, calibration instructions, etc.?

() No (X) Yes If No, explain:

If Yes, have you determined that it is possible to obtain this literature from the manufacturer?

() No (X) Yes If Yes, give estimated cost (if any): \$ _See Quotation__

If No, submit the package only after confirming availability from manufacturer.

A25.9. Calibrations: Complete list below or check () N/A and go to paragraph A25.10.

Source of calibration service:

(X) BMET (X) MERC (X) Manufacturer () Depot () PMEL

If Manufacturer, justify:

__Manufacturer will be needed until technical training is accomplished and then as needed

Comment on any expected calibration problems or check (X) N/A and skip to paragraph A25.10.

A25.10. Final system acceptance will be performed by:

() MERC () BMET () Requester (X) Other () Not required (explain):

AFMSA/SGSLE will accomplish the Acceptance Test and provide established protocols.

A25.11. Additional comments:

SIGNATURE OF SENIOR BIOMEDICAL EQUIPMENT TECHNICIAN
(Request will not be processed without signature)

PART II - FACILITY MANAGEMENT SECTION

A25.12. Are suitable utilities, as described in paragraph A25.4.1., available? No Yes

If No, explain actions being taken to provide them:

What is the earliest date utilities will be available? _____

A25.13. Estimated cost of facility modification described in paragraph A25.4.4. needed for installation of this unit:

\$ _____

Date AF Form 332 was or will be submitted to CE: _____

(Must match date in paragraph **A25.4.6.** above)

Estimated earliest possible completion date of these facility modifications: _____

A25.14. Additional comments: _____

SIGNATURE OF FACILITY MANAGER

(Request will not be processed without signature)

Part III – Information Systems Section

A3.1. Does equipment require connectivity to medical Center Local area network (LAN)

No Yes

If Yes, explain type of connectivity required i.e. TCP/IP, Ethernet, Token Ring, etc:

TCP/IP _____

What is the data rate required for connectivity i.e. 10Mbs, 100Mbs, etc.?_100 Mbs or greater_

A3.2. Does equipment require a host server? No Yes

If Yes, is server operating system Microsoft Windows 2000 or higher? No Yes

If No, what operating system is being used? _____

If Yes, do you require server administration support? No Yes

Does system purchase include server administration training No Yes

If Yes, are funds available to fund travel and per diem to attend training No Yes

Location of training: _See Quotation_____

A3.3. Does system require remote dial up access via modem lines or Internet? No Yes

If Yes, Modem Internet

If system requires modem lines has Remote Access System account been requested from SGSI?

No Yes

Note, requester must submit application for Remote Access System account prior to gaining access to Air Force Network. Internet connectivity requires data encryption on both ends.

Explain purpose of remote access: _____

A3.4. Is the process of applying software updates and security patches outlined in A25.4.7 acceptable? Yes No

If not, explain an acceptable solution for updating software and applying patches:

A3.5. Additional comments:

SIGNATURE OF INFORMATION SYSTEMS OFFICER

(Request will not be processed without signature)

Digital Dental Vendor Contact List

Force3

Contact Name: Wes Osborne, Sales Manager

Phone: 800-931-0204

Cell Phone: 443-994-1125

Email: wes.osborne@force3.com

Address: 2147 Priest Bridge Dr.
Crofton, MD 21114

Website: www.force3.com

Mandaree Enterprises

Contact Name: Joseph P. Fish, Business Manager

Phone: 512-260-3592

Email: joe.fish@mandaree.com

Address: 1909 Coachlamp Dr.
Cedar Park, TX 78613

Website: www.mandaree.com

Digital Dental-Acceptance Testing Checklist

Document	Completed
	<input type="checkbox"/>

In Progress



DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON, DC

MEMORANDUM FOR HQ USAF/SGR

NOV 03 2005

FROM: HQ AFMSA/SGRTS
5201 Leesburg Pike, Suite 1511
Falls Church, VA 22041

SUBJECT: Certification Recommendation for Approval to Operate (ATO) for Digital Dental Radiography System (DDRS) Version 1.0

According to the provisions of DoD 5200.40, DoD "Information Technology Security Certification and Accreditation Process" and AFI 33-202v1, "Network and Computer Security," an ATO is recommended for DDRS Version 1.0 for a period of three years.

The analysis revealed that DDRS Version 1.0 meets minimal security requirements as stated in the System Security Authorization Agreement (SSAA). The residual risk(s) of operating this system are identified in Appendix Q of the SSAA. It is my recommendation that outstanding vulnerabilities in Appendix Q be mitigated as identified in the Plan of Action and Milestone located in Appendix X of the SSAA.

I certify that an appropriate level of protection exists and recommend you sign the accreditation letter at Attachment 1 granting a three (3) year ATO. This office will retain a copy of this ATO recommendation letter as a permanent record. My point of contact is Hayley Bryan-Hardy at (703) 681-7050.

A handwritten signature in black ink, appearing to read "SD Williams".

STEVEN D. WILLIAMS, CIV, DAF
CISSP, ISSMP, CISM, CHS-III, MCSE, CCNA
Certification Authority

Attachment:
Accreditation Letter
Appendix Q



DEPARTMENT OF THE AIR FORCE
HEADQUARTERS UNITED STATES AIR FORCE
WASHINGTON, DC

JAN 27 2006

MEMORANDUM FOR AFMSA/SGSLE

FROM: HQ USAF/SGR
5201 Leesburg Pike, Suite 1400
Falls Church, VA 22041

SUBJECT: Approval to Operate (ATO) for Digital Dental Radiography System (DDRS)
Version 1.0

According to the provisions of DoD 5200.40, DoD "Information Technology Security Certification and Accreditation Process" and AFI 33-202v1, "Network and Computer Security", an ATO is granted to Digital Dental Radiography System (DDRS) Version 1.0. This ATO is granted for three (3) years. This approval is based on my review of the Certification Authority's recommendation letter and the System Security Authorization Agreement (SSAA). This memorandum is my formal declaration that satisfactory levels of security requirements have been properly implemented and that an appropriate level of protection exists within the DDRS application. The DDRS application is authorized to process data up to the sensitive level.

Appendix Q identifies the individual residual risk elements and recommendations. To ensure that the highest level of security is present within the system, implement the recommended countermeasures found in Appendix Q. If a technical solution can be applied in the place of a policy solution, it must be achieved using valid documentation proving that the technical solution has been accomplished. The following condition also applies:

- The program office has provided HQ USAF/SGR with a Plan of Action and Milestone (POA&M) to the outstanding vulnerabilities found in Appendix Q of the SSAA. The vulnerabilities will be corrected on the dates identified in the POA&M in Appendix X of the SSAA.

It is the responsibility of the Program Office to implement the recommended countermeasures in Appendix Q; noncompliance may result in revocation of this Accreditation Letter. It is the responsibility of the senior official in charge of the system to ensure that this accreditation is maintained. Any changes in configuration, mode of operation, or other modification must be evaluated to determine its impact on the system's security posture.

The Program Office must ensure reaccreditation takes place six (6) months prior to the expiration of this accreditation letter. This office will retain a copy of this ATO letter as a permanent record. My point of contact is Steven D. Williams at (703) 681-4144.

A handwritten signature in black ink, appearing to read 'P. Demitry', with a long horizontal stroke extending to the right.

PETER F. DEMITRY, Col, USAF, MC, CFS
Designated Approving Authority

Digital Dental-Site Prep Requirements

The following site preparations must be considered prior to digital dental equipment installation. Follow the attachment 27 for complete installation requirements review:

Issue	Y/N	Comments
Any new tubeheads due-in?	<input type="checkbox"/>	
Have you reviewed your DCO timeline to see how it will affect your current dental configuration?	<input type="checkbox"/>	
Has a bioenvironmental study been accomplished or is one planned?	<input type="checkbox"/>	
Any pre-existing structural renovation projects?	<input type="checkbox"/>	
Any central IT buys planned for your facility that would affect the current IT configuration of your dental clinic?	<input type="checkbox"/>	

In Progress

Digital Dental Checklist

Follow this checklist to ensure all requirements are met for your digital dental solution:

Checklist Item	Completed
Configuration worksheet completed.	<input type="checkbox"/>
AF Form 601 package completed...includes signed 601, 13 point justification, Attachment 27, Breakout Attachment, vendor quote, signed coversheet, and product specifications.	<input type="checkbox"/>
Final 601 package signed by MAJCOM and forwarded to AF Clinical Engineering for review.	<input type="checkbox"/>
Site prep requirements checklist completed and all items requiring action have been identified and planned for.	<input type="checkbox"/>
Network certification process has been initiated. ICTO/IATO has been requested.	<input type="checkbox"/>
PACS administrators have been identified.	<input type="checkbox"/>
Users and maintainers have been identified for on-site training.	<input type="checkbox"/>
Out-year maintenance, software update requirements have been identified for local funding.	<input type="checkbox"/>
Local funding for structural renovation and room modifications have been identified.	<input type="checkbox"/>

Digital Dental FAQ

The following answers frequently asked questions regarding the implementation of digital dental radiography at your facility. Answers are divided into administrative, technical, maintenance/support, and questions from the field. To answer any specific questions not addressed below, please contact AF Clinical Engineering at DSN 343-7445:

Administrative

1. Who do I contact when my facility has decided to go digital? AF Clinical Engineering is the POC for the Digital Dental Radiography System (DDRS) initiative. As soon as your facility makes the decision to convert to digital technology, please contact them DSN 343-7445 to initiate the process. They will provide you with the initial steps to digital dental implementation.
2. Who should be involved with the digital dental project? At a minimum, Dental, Medical Logistics, Medical Maintenance, Facility Management, and Information Technology should be a part of the implementation effort. It is critical that all parties be involved from inception to ensure all acquisition, sustainment, network connectivity, and facility modifications are identified early in the process.
3. Is there a standard formula to use when developing the digital solution for my site? Yes, there is a standard configuration that will help you to develop a macro-level cost/configuration figure. This document is included in the “Digital Dental Primer” that was forwarded to your facility. The spreadsheet is based on Dental Care Optimization principles and optimal sensor usage for all facilities. It is designed to be a planning tool for future acquisition/funding.
4. What documents do I need to complete to procure digital dental equipment? A complete acquisition package consists of an AF Form 601 (signed by the Group CC and MAJCOM Logistics), a 13 point justification, Attachment 27, Modality breakout attachment, and vendor quote. Standard templates have been included in the “Digital Dental Primer” forwarded to your facility.
5. Do I have to contact all of the vendors for the digital solution? No, under the central effort to procure digital dental radiography AF-wide, the decision was made to contract through an integrator to assist in the overall acquisition process. It is the role of the integrator to coordinate the acquisition of all digital dental radiography modalities to include the procurement, installation, acceptance, and first year warranty support. The integrator will be your one stop shop for vendor contact.
6. Where do I send the completed package of information? The completed package should meet your local ERAA board and should be forwarded to your Group CC for signature. Upon signature, the package should be forwarded to your MAJCOM for approval, followed by submission to AF Clinical Engineering for QC. From here the package will go to the Air

Force Dental Technology (AFDenT) board for final approval. The routing flowchart has been included in the “Digital Dental Primer” forwarded to your facility.

7. Can I use local funds to procure my digital dental solution? Local funds can be used, however, a central effort is underway to outfit the entire AF with digital dental radiography solutions. If you have local funding available, please contact AF Clinical Engineering to coordinate the request to use local funds.
8. Can I buy high-end printers as a part of the digital solution? High-end printers are the exception, not the rule. High-end printers such as Codonics are relegated for large processing facilities such as Maxwell and the Air Force Academy. If you would like to request a Codonics printer as a part of your digital dental solution, you will be required to provide justification that must be approved by the AFDenT prior to purchase.

Technical

1. What does the typical digital dental radiography solution consist of? The typical configuration consists of direct capture sensors, digital panoramic radiography, charged-phosphor (PSP), workstations if required, and a standard desk-jet printer. The standard quantities for each can be found by completing the Standard Configuration spreadsheet. Follow the guidance set forth in the “Digital Dental Primer” and you will come very close to your final solution. This information gained from the standard configuration spreadsheet should be cross-referenced with your vendor quote to ensure that your facility receives the proper configuration.
2. Has DECS reviewed the digital dental modalities? All modalities identified as part of the digital dental solution have been reviewed by DECS. A complete list of the reviews can be viewed by visiting the DECS website.
3. Does the digital solution use standard acquisition software? Yes, the digital solution uses MEDICOR software for image acquisition and image manipulation.
4. Where will my images be stored in the facility? Images will be stored on the MiPACS server. The server is robust and can store a vast quantity of dental images. Images can be viewed and retrieved from the local MiPACS.
5. Will the images be stored in a long term archive? Yes. Images will be redundantly stored in a long term archive. Right now, the archive is not established. A final determination must be made on what overall long term archive solution to establish. Options include a MEDICOR developed LTA, the use of existing medical PACS, the use of the existing COHORT database, or the use of the Army DEVVA archive. Regardless of the final decision, a long term archive will soon be in place to satisfy disaster recovery requirements.

6. Will I require a Certificate of Networthiness for the digital solution? Yes, a Certificate of Networthiness (CON) is required. A CTO currently exists for DDRS. You will be required to request a CTO/ATO for your respective MAJCOM. CON is pending on DDRS.
7. What are the minimum specifications for my computers running the MEDICOR software? Windows XP, Pentium 4, minimum 512 MB RAM, 128 MB video card
8. Who will conduct final acceptance on the digital solution? Final acceptance testing will be conducted by local maintenance and IT personnel. AF Medical Physicists are currently developing, in conjunction with AF Clinical Engineering, the acceptance testing protocols for DDRS.

Maintenance/Support

1. Who do I call if I have problems with my digital solution after acceptance? Force3 will provide maintenance and user support for a period of one year following acceptance of DDRS. Local maintenance, IT personnel, and the identified PACS administrator will provide first look support. If the problem cannot be solved at the local level, contact Force3 and they will coordinate support for all modalities.
2. Who will maintain the digital solution? Local maintenance and IT personnel.
3. I'm not familiar with the MEDICOR software and the digital equipment, will I receive any training? Yes, you will receive training. On-site training will be provided to users, maintainers, and IT personnel. AETC/SGD is also working on developing a digital dental radiography training program for bases newly implementing digital radiography as well as for the dental assistant school house.

Questions from the field

1. Are the requesting bases supplying the PC's? Yes/No. We have a mix. Most facilities opted to use the existing IT infrastructure to support the digital rad initiative, while a few actually requested new workstations. AFMC will be using the existing IT hardware.
2. Is any remote access needed or will it be required in the future (doctors reading from home, another facility, etc.)? No remote access at this time
3. Who will be responsible for accepting the system? Acceptance testing will be a combination of the manufacturers and local IT/BMETs. We are currently developing acceptance testing protocols.
4. Will it be connected to a CHCS or equivalent scheduling system? Is the data from the 2 systems compatible or will there have to be a broker? The digital solution will not be

connected to a scheduling system. The dental community uses CDA for scheduling. In the future, the dental community wants to integrate with scheduling

5. Is this going to be on a subnet or stay on the normal hospital network? VPN behind MEDICOR PACS (MiPACS)
6. Will static IP's be required? If so, how many? Yes, static IP's will be required. The total number will depend on the number of software licenses that have been requested. Varies per facility.
7. Is this an FDA regulated software program? Will we need to block patches being run to the PC's? Yes, this is FDA regulated software. HQ AETC/IT has developed a patch management plan as part of the SSAA. All patches will need to be validated by MEDICOR before local installation can occur.
8. Who will maintain the contracts on the system? Local personnel will maintain the contracts. All equipment comes with one year warranty. After expiration, the local facility will be responsible for any extended maintenance and support (local O&M cost).
9. Are there going to be any WRM applications? No
10. Who is going to be trained to maintain the server at Wright-Patterson? User training, administrator training, and maintenance training is included in the contract. Individuals identified for the training is a local decision.
11. Are there going to be any modem lines or network service lines that would breach the firewall? The only potential breaches are for migration to long-term regional storage (if capabilities exist for your MAJCOM)
12. Will ports need to be opened to access the system? Not for the individual site solutions. The dental community wants to have regional/central archiving capabilities, which would then necessitate the opening of ports. More to follow on this as we progress down the archiving path.
13. Will this be an FDA approved system or will it be a beta test site? FDA approved
14. Is there going to be a certificate of network worthiness? A CTO was issued for AETC. It was forwarded to AFCA for the CON. Looking at the end of May for the CON issue.
15. What is the recommended specs for memory, hard drive, RAM, etc. on the PC's being used (will existing PCs seem too slow even if they meet minimum requirements?) Windows XP, Pentium 4, minimum 512 MB RAM, 128 MB video card
16. Who is going to load the software on the PC's? MEDICOR will install the software at each facility

17. Has it been stated that any software upgrades have to be certified before being installed?
Any software upgrades will be the responsibility of the local facility (O&M). Certification will be determined by the degree of the upgrade and will be handled centrally to ensure standardization across the board, i.e. if MEDICOR releases a major update, an enterprise decision will have to be made and coordinated prior to purchase/install.
18. Will the facility get service manuals on the plate readers? The facility will receive two service manuals for all equipment and software. (Two for MEDICOR, two for Planmeca, two for Schick, etc.)
19. Is there a training video or continuing education due to military members PCSing?
AETC/SGD is working on developing a dig rad training program for bases newly implementing dig rad as well as for the dental assistant school house.
20. Who will be onsite to troubleshoot problems with the system and how will they be trained?
Force3 will be on site for a short period after the installation to handle any initial quirks. User, administrator, and maintenance training will be provided as part of the contract. Warranty will cover all issues for the first year. After this, the sites will have to make a decision whether they can maintain locally with the BMETs and IT, a first look contract, or a full service contract
21. Since this is DICOM 3.0 compliant, could X-rays be read from another PACS system or transferred to another PACS system? Transfer to existing PACS is definitely an option. The MEDICOR solution comes with a fairly robust mini-PACS, but the plan is to migrate to long term regional/central storage. The plan is to have WPAFB as the location for the central archive.
22. Can we load software onto existing PACS system to view dental PACS in Surgery? Are you planning to connect your Dental MiPACS with your existing medical PACS? The images are DICOM and you should not have to rely on the MEDICOR software to view an image. If you need to manipulate the image (dental specific) you will have to use MEDICOR software. The connection (MiPACS to PACS should be fairly simple. Just a matter of IP addresses, AE_Titles, and a virtual tunnel).