



Working together for a healthier world

*New Hemodialysis Center Start-up and Validation Best
Demonstrated Practices and Procedures*

Christopher E. Atwater Sr.
Director of Technical Operations



Validation Process

Careful analysis of a number of plane crashes has identified five main reasons, although many accidents are caused by a combination of factors. These five causes are

human error

mechanical defects

weather problems

air traffic controller/other
ground staff error

other causes

Boeing 737-800 Procedure Checklist

ELECTRICAL POWER UP Procedure		PASSENGER SIGNS	SET
BATTERY SWITCH	GUARD CLOSED	WIPER SELECTORS	PARK
STANDBY POWER	GUARD CLOSED	WINDOW HEAT	ALL ON
ALTERNATE FLAPS	GUARD CLOSED	PROBE HEAT	OFF
WIPER SELECTOR	PARK	WING ANTI-ICE	OFF
ELEC HYD PUMPS	OFF	ENGINE ANTI-ICE	OFF
LANDING GEAR LEVER	DOWN	HYDRAULIC PANEL	Set
If External Power is needed:		AIRCON PANEL	Set
GND PWR AVAIL	GND PWR SWITCH ON	PACKS= AUTO/HIGH, ISO VALVE= OPEN, ENG BLD= ON, APU BLD= ON	
If APU Power is needed:		CABIN PRESS PANEL	SET
Verify ENG1, APU, ENG2 fire switch IN		LIGHTING PANEL	SET
OVERHEAT DET SWITCH	NORMAL	POSITION= ON, LOGO= AS REQ, ANTICOL= OFF, OTHERS= OFF	
TEST SWITCH	Hold to FAULT/INOP	IGNITION SELECT SW	IGN L or R (ALTERNATE EACH FLIGHT)
OVHT/DET & APU DET INOP LIGHT	Verify Illuminated	ENGINE START SWITCH	OFF
TEST SWITCH	Hold to OVHT/FIRE	TUNE ATIS AND NOTE DETAILS	
MASTER FIRE WARN	PUSH	CALL FOR DEPARTURE CLEARANCE	
EXTINGUISHER TEST	CHECK	MODE CONTROL PANEL	SET
TEST SWITCH	POS TO 1 HOLD then RELEASE (repeat for 2)	EFIS CONTROL PANEL	SET SET MINS DEP AERO, SET QNH
APU	START	OXYGEN	TEST AND SET
APU GENERATOR BUS	ON	CLOCK	SET
WHEEL WELL FIRE	TEST	DISPLAY SELECT PANEL	SET
FIRE BELL CUTOUT	PUSH	DISENGAGE LIGHT TEST	HOLD TO 1 (repeat 2)
PRELIMINARY PREFLIGHT Procedure (Capt or FO)		FLIGHT INSTRUMENTS	CHECK NO FLAGS, FMA BLANK, FD
IRS MODE SELECTORS	OFF, then NAV	GROUND PROXIMITY	CHECK
VOICE REC SWITCH	ON	LANDING GEAR PANEL	SET DOWN, 3 GRN, NO RED
PSEU LIGHT	EXTINGUISHED	AUTO BRAKE	RTO
GPS LIGHT	VERIFY EXTINGUISHED	ANTISKID INOP	VERIFY EXTINGUISHED
SERVICE INTERPHONE	OFF	ENG DISPLAY CONTROL	SET AUTO, AUTO, RATE
ENGINE PANEL	SET	ENGINE INSTRUMENTS	CHECK
OXYGEN PANEL	SET	CARGO FIRE PANEL	CHECK DET SW= NORM, PUSH TEST, PUSH MASTER FIRE, VFY ILLUM FWD AFT DET EXTINGUISHED
LANDING GEAR LIGHTS	VERIFY ILLUMINATED	RADIO TUNING PANEL	
FLIGHT REC SWITCH	GUARD CLOSED	TRANSPONDER PANEL	SET
PARKING BRAKE	ON	STAB TRIM OVERRIDE	GUARD CLOSED
CDU PREFLIGHT Procedure		SEAT/RUDDER PEDALS	ADJUST
The initial data and Nav data entries must be completed before the Preflight Procedures. Performance Data entries must be complete before the Before Start Checklist		PREFLIGHT Procedure - CAPTAIN	
CDU PREPARATION	ENTER DATA	LIGHTS	TEST
PREFLIGHT Procedure - FO		MODE CONTROL PANEL	SET
FLIGHT CTRL PANEL	CHECK	EFIS CONTROL PANEL	SET SET MINS DEP AERO, SET QNH
NAVIGATION PANEL	SET	OXYGEN	TEST AND SET
DISPLAYS PANEL	SET	CLOCK	SET
FUEL PANEL	SET	NOSE WHEEL STEERING	GUARD CLOSED
ELECTRICAL PANEL	SET	DISPLAY SELECT PANEL	SET
OVERHEAT AND FIRE PROTECTION PANEL	CHECK	DISENGAGE LIGHT TEST	HOLD TO 1 (repeat 2)
APU SWITCH	START	STAB OUT OF TRIM	LIGHT EXTINGUISHED
EMERG EXIT LIGHT	GUARD CLOSED		

Page 1 of 4

kb@kennair.com.au – March 2015

***New Dialysis Center require the
same system validation***

Critical Areas Requiring Validation

Water Systems

Concentrate and Bicarbonate Delivery Systems

Dialysis Machines

Ancillary Equipment

Bacteriological Testing and Monitoring

Hazardous Materials

Biomed and Operation Records



Water Systems

Water Systems
AAMI water analysis collected from Last H2O out and Tap H2O Out
AAMI Water Analysis results within acceptable limits
RO System Flow Diagram Complete and provided by vendor
Label RO system with component identification, valves, gauges and sample ports according to DaVita policies
Verify Pre-treatment bypass lock outs in place
Verify RO system ON/OFF levels on storage tank are labeled
Verify 100 gallon mark on holding tank for system disinfections is labeled
Verify U/F filters have been installed?
Verify RO system disinfections has been performed and documented if applicable
Verify all timers set appropriately with backwash times labeled on each component?
Has EBCT been calculated and posted on Carbon Tanks?
Are the RO Start-up, Shut-down, and Bypass procedures posted?
Verify the RO Audible and Visual alarms are functional?
Are all Water Test Kits available (Hardness and Total Chlorine)?
Is water treatment room arranged for easy access and functionality?
Is central sample sink properly labeled, if applicable?
Allow adequate RO system run time, adjust parameters, and create Daily Water Treatment and Monthly Water Treatment Logs
Begin documentation of Daily Water Treatment Log
Begin documentation of Monthly Water Treatment Log



Concentrate and Bicarbonate Delivery Systems

Concentrate and Bicarbonate Delivery Systems

Verify concentrate mixer been received and installed?

Verify concentrate holding tanks and distribution pumps been installed and entered in **BART**?

Water station boxes completed with central Acid and Bicarb distribution fittings and labels

Are all appropriate tests kits available for Acid and Bicarb testing?

Installation service records have been completed, including Electrical Leakage *as applicable* through **BART** and placed in equipment binder

Verify first batch of concentrate results with acceptable limits (received from) manufacturer obtained and filed?



Dialysis Machines

Dialysis Machines

Have dialysis machines and SN been received?

Dialysis Machines have been installed by manufacturer or Biomed Teammate

Installation service records for **APPLICABLE INITIATIVES** have been documented and copy of service ticket placed in equipment binder

Electrical Leakage has been completed on all Dialysis Equipment and filed

Dialysis Machines numbered for identity

Obtain electrolytes from dialysis machines and verify results

Verify integrated heat installed (Heat system clinic)



Ancillary Equipment

Accuracy Testing Meters
Myron L: D1, D2 or Phoenix Meter & Tri-Station, ready for use with calibration certificates on file
Biomed Dialysate Test Meter in facility with calibration certificate on file
Voltmeter meter in facility with calibration certificate on file
Electrical Safety Analyzer in facility with calibration certificate on file
Dialysis Machine PM equipment in facility (gauges, burettes, etc.)
Biomed Tools in facility

Bacteriological Testing and Monitoring

Bacteriological Monitoring - Documentation
Inlet #1 - 3 consecutive days of Bacterial and Endotoxin samples from Water Treatment system (first, last, dry acid, & bicarb H2O out)
Inlet #2 - Bacterial and Endotoxin samples from Water Treatment system (first, last, dry acid, & bicarb H2O out)
Inlet #3 - Bacterial and Endotoxin samples from Water Treatment system (first, last, dry acid, & bicarb H2O out)
Inlet #4 - Bacterial and Endotoxin samples from Water Treatment system (first, last, dry acid, & bicarb H2O out)
Inlet #1 - Dialysate Bacterial and Endotoxin samples from all dialysis machines
Inlet #2 - Dialysate Bacterial and Endotoxin samples from all dialysis machines
Inlet #3 - Dialysate Bacterial and Endotoxin samples from all dialysis machines
Inlet #4 - Dialysate Bacterial and Endotoxin samples from all dialysis machines
Week # 1 Water System, Dialysate Bacterial and Endotoxin results within acceptable limits and entered on trending log
Week # 2 Water System, Dialysate Bacterial and Endotoxin results within acceptable limits and entered on trending log
Week # 3 Water System, Dialysate Bacterial and Endotoxin results within acceptable limits and entered on trending log
Week # 4 Water System, Dialysate Bacterial and Endotoxin results within acceptable limits and entered on trending log
All Bacterial and Endotoxin results entered into a Trending Log format as required (manual or Snappy column report) and placed in Water Quality Binder



Hazardous Materials

Hazardous Materials
Acid concentrate storage containers have proper HMIS labels
Acid concentrate secondary containers have proper HMIS labels
Bicarb Distribution system have proper HMIS labels
Bicarb secondary containers have proper HMIS labels
Secondary bleach containers have proper HMIS labels
Laboratory Refrigerators are properly labeled with Biohazard Label
Hazardous Materials are stored according to manufacturers specifications
Hang Auto Dilutor and complete Auto Dilutor Log Book
Post PAA Temp Log in storage room with digital thermometer
Post chemical spill kit



Biomed and Operation Records

Biomed and Operation Records
Equipment PM Schedule Complete and in place
Culture Schedule complete and in place
Dialysis Equipment Service binder complete and in place (to include: Electrical Safety testing for dialysis machines)
Water Treatment Records logs / binder (to include Daily Water Treatment log, Total Chlorine log, Total Chlorine Breakthrough log) complete and in place
Water Quality binder (Includes: Culture Schedule, AAMI Analysis, Trending Logs, & Monthly results) complete and in place
Ancillary Equipment Service binder (Includes: Ancillary Equipment PM's & Electrical Leakage, Phoenix Meters, Neo-2, Voltmeter and Safety Analyzer)
All Facility specific Policies and Procedures in place
Biomed teammate files Documented & Filed including manufacturer certificates
Has Bicarb system been properly disinfected with verified procedures?
Bicarbonate Mixer & loop validation - Bacterial and Endotoxin sampling completed, within specs., reviewed by Governing Body
Facility Specific Bicarb Mixing and Disinfection logs / binder Completed, Modified, Verified, & Approved by Governing Body and given to FA and uploaded to P&P
Acid distribution system - Obtain Calcium and Potassium results on primary and secondary loop utilizing snappy test #0479
Training of Operation teammates on general & facility specific P&P's Completed, Documented, & Filed
Attend Governing Body to review Biomed documentation



Questions

Email:
chris.atwater@bolteam.org

What's: +14043948206

Website:
BridgeOfLifeInternational.org

