PHILIPS

Monitor/
defibrillator

Efficia DFM100

At the core of your emergency response

To deliver high levels of care, you need to make quick, informed decisions – at the scene of an emergency and across the entire course of treatment. You need your equipment to be easy to use as you care for a patient, monitor developments in the patient's condition during transport to the hospital, and care for your patient in the hospital. We designed the Philips Efficia DFM100 monitor/defibrillator so you can meet the demands of patient care in the pre-hospital and hospital environment effectively and consistently. With field-proven Philips technology, the Efficia DFM100 offers core functionality with a scalable feature set and improved cost of ownership, allowing you to enhance patient care, no matter where the patient is located.

Key advantages

- Dependable and easy to use
- Scalable feature set
- Enhanced cost of ownership

Specifications

General

Parameter	Specification
Approximate dimensions	23.5 x 29 x 20.5 cm (9.25 x 11.4 x 8 in) H x W x D
Approximate weight (without battery)	5.66 kg (12.5 lb)
Standard operator position	Within 1 m (3 ft) of the device
Power	Rechargeable lithium ion battery; AC power using a protectively grounded outlet
Alarm tone and voice message volume range	Maximum – 85 dB(A), minimum – 45 dB(A)
Alarm tone volumes	Imminent shutdown – continuous tone alternating between 1000 and 2100 Hz High priority – tone of 960 Hz lasting 0.5 second repeated every second Medium priority – tone of 480 Hz lasting 1 second repeated every 2 seconds Low priority – tone of 480 Hz lasting 0.25 second repeated every 2 seconds
Visual alarm characteristics	High priority (Red) – flashing at 2 Hz with 50% duty cycle (.25-second flash twice every second) Medium priority (Yellow) – flashing at 0.5 Hz with 50% duty cycle (1-second flash every other second) Low priority (Cyan) – constant on

Defibrillator

Parameter	Specification
Waveform	Biphasic truncated exponential; waveform parameters adjusted as a function of patient impedance
Shock delivery	Via multifunction electrode pads or paddles
Shock series	Configurable energy escalation in a series
Leads-off sensing and PCI sensing for pads and paddles	Apply 500 nA rms (571 Hz); 200 uA rms (32 KHz)

Delivered energy accuracy

Nominal delivered energy vs. load impedance

Selected energy	Load impedance (ohms) ±2%						
	25	50	75	100	125	150	175
1 J	1.2	1.3	1.3	1.2	1.1	1.0	0.9
2 J	1.7	2.0	2.1	2.0	1.9	1.7	1.6
3 J	2.6	3.0	3.1	3.2	3.2	3.1	2.9
4 J	3.5	4.0	4.2	4.3	4.4	4.5	4.3
5 J	4.3	5.0	5.2	5.4	5.5	5.6	5.4
6 J	5.2	6.0	6.3	6.5	6.6	6.7	6.5
7 J	6.1	7.0	7.3	7.6	7.8	7.8	7.6
8 J	6.9	8.0	8.4	8.6	8.9	8.9	8.7
9 J	7.8	9.0	9.4	9.7	10	10	9.8
10 J	8.7	10	10	11	11	11	11
15 J	13	15	16	16	17	17	16
20 J	17	20	21	22	22	22	22
30 J	26	30	31	32	33	33	33
50 J	43	50	52	54	55	56	54
70 J	61	70	73	76	78	78	76
100 J	87	100	105	108	111	111	108
120 J	104	120	126	130	133	134	130
150 J	130	150	157	162	166	167	163
170 J	147	170	178	184	188	189	184
200 J	173	200	209	216	222	223	217

The delivered energy accuracy is ±10% or ±1 J, whichever is greater for all energy settings.

Charge times

Less than 5 seconds to the recommended adult energy level (150 J) with a new, fully charged battery installed

Less than 6 seconds to the selected energy level (up to 200 J) with a new fully charged battery installed, even after the delivery of 15 discharges at maximum energy

Less than 15 seconds to the selected energy level while connected to AC power only, even when operating on 90% of the rated mains voltage

The device powers on in manual defibrillation mode, ready to deliver shock in less than:
- 23 seconds with AC power only and at 90% of rated mains voltage
- 15 seconds with a new, fully charged battery, even after 15 discharges of maximum energy

Time from the initiation of analysis in AED mode until ready to deliver shock is less than 20 seconds with:
- AC power only and at 90% of rated mains voltage
- A new, fully charged battery, even after 15 discharges of maximum energy

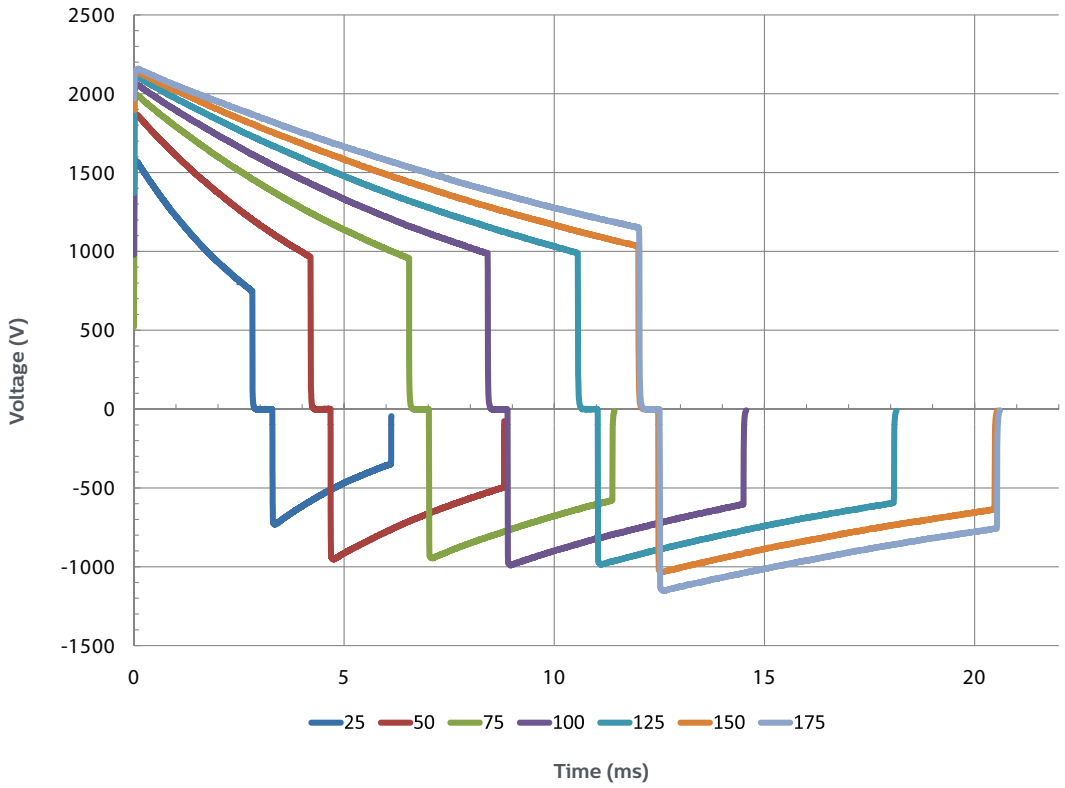
The device powers on in AED mode, ready to deliver shock in less than:
- 32 seconds with AC power only and at 90% of rated mains voltage
- 24 seconds with a new, fully charged battery, even after 15 discharges of maximum energy

Patient impedance range

Minimum: 25 ohm (external defibrillation); 15 ohm (internal defibrillation)
Maximum: 250 ohm; actual functional range may exceed these values

Smart biphasic waveform

Philips smart biphasic waveform at 200 J into 25–175 ohms



Manual defibrillation mode

Parameter	Specification
Manual output energy (selected)	1–10, 15, 20, 30, 50, 70, 100, 120, 150, 170, 200 J; maximum energy limited to 50 J with internal paddles
Controls	On/off therapy knob, charge, shock, sync, ECG lead select, patient selection, print, mark events, reports, alarms, smart select knob
Energy selection	Front panel therapy knob
Charge control	Front panel button; button on external paddles
Shock control	Front panel button; buttons on external or switched internal paddles
Synchronized control	Front panel sync button
Synchronized shock timing	Maximum time from R-wave detected to shock delivered is 25 ms, as measured with oscilloscope from peak of input QRS wave to leading edge of defibrillation discharge into a 50 ohm test load
Indicators	Text prompts, audio alerts, QRS beeper, battery status, ready for use (RFU), external power, sync mode
Armed indicators	Charging and charged tones, flashing shock button on front of panel and on external paddles, energy level indicated on the display

AED mode

Parameter	Specification
AED energy profile	150 J (factory default) for adult, 50 J for infant/child (nominal), into a 50 ohm test load
AED controls	On/off, shock
Text and voice prompts	Extensive text and audible messages guide user through a user-configured protocol
Indicators	Monitor display messages and prompts, voice prompts, battery status, RFU, external power
Armed indicators	Charging and charged tones, flashing shock button, energy level indicated on the display
ECG analysis	Evaluates patient ECG and signal quality to determine if a shock is appropriate and evaluates connection impedance for proper defibrillation pad contact
Shockable rhythms	SMART analysis is designed to shock ventricular fibrillation, ventricular flutter and polymorphic ventricular tachycardia; it is designed to avoid delivering a shock for rhythms that are commonly accompanied by a pulse or rhythms that would not benefit from an electrical shock
Shock advisory algorithm sensitivity	Meets AAMI DF39 requirements and AHA recommendations Adult: ventricular fibrillation – 90% with lower confidence limit (LCL) of 87% Polymorphic ventricular tachycardia and ventricular flutter – 75% with LCL of 67% Infant/child: ventricular fibrillation – 90% with LCL of 87%
Shock advisory algorithm specificity	Meets AAMI DF39 requirements and AHA recommendations Normal sinus rhythm – 99% with LCL of 97% Asystole – 95% with LCL of 92% Other non-shockable rhythms – 95% with LCL of 88%

ECG and arrhythmia monitoring

Parameter	Specification
Inputs	• Up to 3 ECG waves may be viewed on the display and up to 2 waves printed simultaneously • Lead I, II or III is obtained through the 3-wire ECG cable and separate monitoring electrodes • With a 5-lead ECG cable, leads aVR, aVL, aVF and V can also be obtained • Pads ECG is obtained through two multifunction electrode pads
Lead fault	Messages and dashed lines appear on the display if an electrode or lead becomes disconnected
Pad fault	Dashed line appears on the display if a pad becomes disconnected
Heart rate display	Digital readout on the display from 16 to 300 bpm (adult patient category) or 16 to 350 bpm (infant/child), with an accuracy of ±10% or ±5 bpm, whichever is greater
Heart rate and arrhythmia alarms	HR high/low, asystole, VFIB/V-TACH, VTACH, extreme tachy, extreme brady, PVC rate, pacer not capture, pacer not pacing
Common mode rejection	105 dB for leads ECG, 96 dB for pads ECG
ECG size	1/4x, 1/2x, 1x, 2x, 4x, auto gain (1x gain is 10 mm/mV on the printed strip)
ECG waveforms	Displayed at a fixed timebase of 25 mm/second (printer) ±5%, 25 mm/second (display), ±10%
ECG leads-off sensing	3- and 5-lead wires apply <35 nA DC current to patient electrodes, <1.0 uA to other electrodes
Maximum T-wave amplitude	• Device rejects up to 80% of R-wave amplitude for synchronized cardioversion; up to 55% of R-wave amplitude for demand pacing; up to 34% of R-wave amplitude for arrhythmia analysis • Maximum T-wave amplitude when a QRS test signal is 1 mV amplitude and 100 ms duration, with a heart rate of 80 beats per minute used: 18 mm
Frequency response	• ECG AC line filter: 50 or 60 Hz • ECG for display: 0.15–40 Hz, 0.05–40 Hz (IEC 60601-2-27:2011 201.12.1.101.8 a, b), 2.0–20.0 Hz • ECG for printer: 0.05–150 Hz – diagnostic, 0.05–40 Hz – ST monitor (IEC 60601-2-27:2011, 201.12.1.101.8 a, b), 0.15–40 Hz – monitor, 2.0–20.0 Hz – EMS

ECG and arrhythmia monitoring (continued)

Parameter	Specification
Heart rate accuracy and response to irregular rhythm	Meets AAMI standard for ventricular bigeminy (HR=80 bpm); slow alternating ventricular bigeminy (HR=60 bpm); rapid alternating ventricular bigeminy (HR=120 bpm); bidirectional systoles (HR=90 bpm) as measured after a 20 second stabilization time
Heart rate averaging	For heart rates ≥ 50 bpm, heart rate is determined by averaging the 12 most recent R-R intervals. Beats N, P, and V are included. When heart rate drops below 50 bpm, the four most recent R-R intervals are used in the average. Note: For ventricular tachycardia alarms, which have a user-definable PVC run length limit, the heart rate is based on the user-selected PVC length up to 9 PVCs maximum. Heart rate display update time is 1 second maximum.
Pace pulse detection sensitivity	1 mV for a width of 100 µs; 200 µV for a 500 µs width and 200 µV for widths of 500 µs to 2 ms
ECG analog output bandwidth	0.5 to 70 Hz
ECG analog output gain	1 v output per 1 mV input ±10%
ECG analog output delay	Propagation delay time is < 25 ms from ECG input to ECG analog output
Pacemaker pulse rejection capability	Amplitude from ±2 mV to ±700 mV, width from 0.1 ms to 2.0 ms as per IEC 60601-2-27:2011 201.12.1.101.13/ YY 1079 4.1.4.1, except the full overshoot range of IEC 60601-2-27 methods A and B
Pacer pulse detector rejection of fast ECG signals	Slew rate of 1.1 V/s
Heart rate response time	7 seconds for a high heart rate alarm when the rate changes from 80 to 120 bpm, with the alarm limit set at 100 bpm; 6 seconds for a low heart rate alarm when the rate changes from 80 to 40 bpm, with the alarm limit set at 60 bpm
Time to alarm for tachycardia	4 seconds for 206 bpm (1 mV, halved amplitude and double amplitude) and 195 bpm (2 mV, halved amplitude and double amplitude) as measured following a normal 80 bpm rate with upper alarm limit set at 100 and lower alarm limit set at 60 bpm
Patient isolation (defibrillation proof)	• Lead ECG: type CF • SpO_2: type CF • CO_2: type BF • NBP: type CF • Pads and paddles: type BF • Internal paddles: type CF
Other considerations	The Efficia DFM100 is suitable for use in the presence of electrosurgery • Burn hazard protection is provided via a 1 K current-limiting resistor contained in each ECG lead wire • Proper lead placement is important to reduce burn hazards in the event of a defect in the electrosurgical equipment • Do not entangle the ECG cables with the electrosurgical equipment wires; do not place the ECG cabling near the electrosurgical equipment's grounding plate

Display

Parameter	Specification
Size	Approximately 17.8 cm (7 in) diagonal viewing area
Type	Color TFT LCD
Resolution	800 x 480 pixels (SVGA) with 32 brightness levels per color
Sweep speed	25 mm/s ±10% nominal (stationary trace; sweeping erase bar) for ECG and SpO_2; capnogram wave is 6.25 mm/s ±10%
Wave viewing time	6.5 seconds ±10%

Battery

Parameter	Specification
Type	Rechargeable, lithium-ion; see battery label for capacity information
Approximate dimensions	28.5 x 80 x 145.7 mm (1.1 x 3.1 x 5.7 in) H x W x L
Approximate weight	Approximately 0.44 kg (1 lb)
Capacity	With a new fully charged battery, at 20°C (68°F), one of the following: • 100 full-energy charge and shock cycles • 2.5 hours of monitoring (ECG, $EtCO_2$ and SpO_2 continuously monitored and NBP sampled every 15 minutes) followed by 20 full-energy charge and shock cycles • Two hours of pacing (180 ppm at 140 mA with 40 msec pulse) and monitoring (ECG, $EtCO_2$ and SpO_2 continuously monitored and NBP sampled every 15 minutes)
Charge time, with device turned off and AC power connected	With temperature at 25°C (77°F), less than 3 hours to 100% capacity; less than 2 hours to 80% capacity.
Battery indicators	• Battery gauge on battery, capacity indicator on display, power indicators on front of device • Flashing RFU indicator, audio beep and low battery messages on the display for low battery condition • When a low battery message first appears, there is still enough energy for at least 10 minutes of monitoring and 6 maximum energy discharges

Thermal array printer

Parameter	Specification
Continuous ECG strip	The print key starts and stops the strip. The printer can be configured to run in real time or with a 10-second delay. The strip prints the primary ECG lead and a second wave with event annotations and measurements.
Auto printing	The printer can be configured to automatically print on mark events, charge, shock and alarm
Reports	The following can be printed: • Event summary (long or short) • Vital signs trends • Operational check • Configuration • Status log • Device information
Speed	25 mm/s with an accuracy of ±5%
Amplitude accuracy	5% for offset voltages of ±300 mV at 5 Hz
Paper size	50 mm x 20 m (1.9 in x 65.6 ft) W x L

Noninvasive pacing

Parameter	Specification
Waveform	Monophasic
Current pulse amplitude	10 mA to 200 mA if the pulse width is set to 20 ms (5 mA increments); accuracy ±10% or ±5 mA whichever is greater. For a 40 ms setting, the maximum pacing current is 140 mA.
Pulse duration	20 or 40 msec with ±10% accuracy
Rate	30 ppm to 180 ppm (10 ppm increments); accuracy ±1.5%
Mode	Demand or fixed
Refractory period	340 msec (30 to 80 ppm); 240 msec (90 to 180 ppm) ±10%
Universal-function electrodes (pads)	After 60 minutes of pacing with approved defibrillators, the multifunction electrodes (pads) exhibit a post-defibrillation DC offset of less than ±800 mV at ≥ 4 seconds post-shock

SpO_2 pulse oximetry

Parameter	Specification			
SpO_2 measurement range	0–100%			
SpO_2 resolution	1%			
SpO_2 update period	1–2 seconds typical; maximum of ≤ 30 seconds			
Sensor accuracy*	Sensor	Accuracy	Sensor	Accuracy
	M1191B	±2%	989803160611	±3%
	M1191BL	±2%	989803160621	±3%
	M1192A	±2%	989803160631	±3%
	M1196A	±3%		
	M1196S	±3%		
Ambient light sensitivity	Interference from fluorescent light is <2% SpO_2 under the following conditions: 0.3 and 1% perfusion, 50 nA/mA transmission, 10 to 1000 lx light intensity, 50–60 Hz power line frequency ±0.5 Hz line frequency.			
SpO_2 alarm range	• Low limit: 50–99% (adult and infant/child) • High limit: 51–100% (adult and infant/child)			
SpO_2 and pulse high/low alarm signal generation delay	10 seconds			
SpO_2 response time (90 to 80%)	Average 18.9 seconds, standard deviation 0.88 seconds			
SpO_2 and pulse averaging time	10 seconds			
Emitted light energy	≤ 15 mW			
Wavelength range	500–1000 nm (information about wavelength range can be useful to clinicians, especially those performing photodynamic therapy.)			
Desat alarm signal generation delay	20 seconds			
Pulse rate measurement range	30–300 bpm			
Pulse rate resolution	1 bpm			
Pulse rate accuracy	±2% or 1 bpm, whichever is greater			
Pulse response time (90 to 120 bpm)	Average 18.0 seconds, standard deviation 0.86 seconds			
Pulse alarm range	• Low limit: 30–295 bpm (adult and infant/child) • High limit: 35–300 bpm (adult and infant/child)			

*Specified accuracy is the root-mean-square (RMS) difference between the measured values and reference values.

Accuracy outside the range specified for each sensor is not indicated. The above referenced sensors were validated for use with the Efficia DFM100 using the Philips picoSAT II SpO_2 module with Fourier Artifact Suppression Technology (FAST).

While the SpO_2 module is able to report values below 70% and alarm limits can be set below 70%, the accuracy of measurements less than 70% has not been validated.

SpO_2 accuracy was validated in human studies against arterial blood sample references measured with a CO oximeter. In a controlled desaturation study, healthy adult volunteers with saturation levels between 70–100% SaO_2 were studied. The population characteristics for those studies were approximately 50% male and 50% female, ranging in age from 19–39, with skin tone from light to dark.

Pulse oximetry equipment measurements are statistically distributed, therefore only two-thirds of pulse oximeter equipment measurements can be expected to fall within ±Arms of the value measured by a CO oximeter.

Functional test equipment designed for SpO_2 testing cannot be used to assess the accuracy of the SpO_2 readings.

The Efficia DFM100 is calibrated to display functional oxygen saturation.

$EtCO_2$

Parameter	Specification
Weight	Mainstream: 78 g (2.75 oz); sidestream: 272 g (9.6 oz)
Dimensions	Mainstream: 43 x 33 x 23 mm (1.69 x 1.29 x .90 in) W x H x L Sidestream: 66 x 38 x 89 mm (2.6 x 1.5 x 3.5 in) W x H x L
Range	0–150 mmHg
Resolution	1 mmHg (0.1 kPa)
Accuracy	0–40 mmHg ±2 mmHg; 41–70 mmHg ±5% of reading; 71–100 mmHg ±8% of reading; 101–150 mmHg ±10 % of reading; gas at 25°C
Drift of measurement accuracy	Over any 24 hour period, the specified measurement accuracy is maintained
Warm-up time	2 minutes at 25°C
System response time	Sidestream: 3.5 seconds typical
Alarm delay time	After alarm condition has been met: mainstream – less than 5 seconds; sidestream – less than 8 seconds; measurement method: peak $EtCO_2$ value within a 10-second window
Sample flow rate	Sidestream – 50 ml/minute ±10 ml
Alarm range	• Low limit: 10–140 mmHg (adult, infant/child) • High limit: 20–145 mmHg (adult, infant/child)

Airway respiratory rate (AwRR)

Parameter	Specification
Range	0–150 rpm
Resolution	1 rpm
Accuracy	±1 rpm
Alarm range	• Low limit: 0–99 rpm (adult, infant/child) • High limit: 10–100 rpm (adult, infant/child)
Alarm delay time	After alarm condition has been met; mainstream – less than 5 seconds; sidestream – less than 8 seconds; measurement method: AwRR – based on the last 8 detected breaths; apnea – following the configured apnea delay time

Noninvasive blood pressure (NBP)

Parameter	Specification				
Pressure range	Measurement	mmHg		kPa	
		Adult	Infant/Child	Adult	Infant/Child
	Systolic	30–255	30–135	4–34	4–18
	Diastolic	10–220	10–110	1.3–29.3	1.3–14.7
	Mean	20–235	20–125	2.7–31.3	2.7–16.7
Initial pressure	160 mmHg/21.3 kPa for adults 120 mmHg/16 kPa for infant/child				
Maximum pressure	300 mmHg/40 kPa				
Overpressure safety limits	290 mmHg/38.6 kPa				
Cuff inflation time	75 seconds maximum				
Pressure transducer accuracy	±3 mmHg over the range 0–300 mmHg/0–40 kPa				

NBP (continued)

Parameter	Specification				
Alarm range	Measurement	mmHg		kPa	
		Adult	Infant/Child	Adult	Infant/Child
	Systolic high limit	35–255, 160	35–135, 120	4.5–34, 21	4.5–18, 16
	Systolic low limit	30–250, 90	30–130, 70	4–33.5, 12	4–17.5, 9
	Diastolic high limit	15–220, 90	15–110, 70	2–29.5, 12	2–15, 9
	Diastolic low limit	10–215, 50	10–105, 40	1.5–29, 7	1.5–14.5, 5
	Mean high limit	25–235, 110	25–125, 90	3.5–31.5,15	3.5–16.5, 12
	Mean low limit	20–230, 60	20–120, 50	3–31, 8	3–16, 7
Auto mode repetition time	1, 2.5, 5, 10, 15, 30, 60 or 120 minutes				
Maximum measurement time	120 seconds				
Interconnect tube length	989803177471 connect tubing 3.0 m (9.24 ft)				

Patient data storage

Parameter	Specification
Internal event summary	The Efficia DFM100 can store up to 8 hours of 2 continuous ECG waves, 1 pleth wave, 1 capnogram wave, research waves (AED mode only) events and trending data per event summary. There is a maximum capacity of approximately 50 event summaries of approximately 30 minutes in length.

USB device

Parameter	Specification
Correct drive	Use the Philips USB drive that came with your device

Environmental

Parameter	Specification
Temperature	Operating temperature for the device: 0°C to 45°C (32°F to 113°F); operating temperature range for $EtCO_2$: 0°C to 40°C (32°F to 104°F); storage/transport temperature range for the device without battery: -20°C to 70°C (-4°F to 158°F)
Setting time to 20°C	Time required for device to warm from -20°C before use is 80 minutes; time required for device to cool from 70°C before use is 80 minutes
Humidity	15% to 95% relative humidity • $EtCO_2$ measurement meets all specifications during and after exposure to humidity conditions from 10–90% • Printer paper may jam if the paper is wet • Thermal printer may be damaged if wet paper is allowed to dry while in contact with printer elements
Atmospheric pressure range/ operation and storage	1060 mbar to 572 mbar; -382 to 4,568 m (-1253 to 14,986 ft)
Shock	Operating: half-sine waveform, duration ≤ 11 ms, acceleration ≥ 15.3 G, 3 shocks per face. Non-operating: trapezoidal waveform, acceleration 30 G, velocity change 7.42 m/s ±10%, 1 shock per face.

Environmental (continued)

Parameter	Specification
Vibration	**Operating random**

Frequency (Hz)	Slope (dB/octave)	PSD $(m/s^2)^2/Hz$
10–100	—	1.0
100–200	-3.0	—
200–2000	—	0.5

Test duration: 10 minutes/axis x 3 axes; 30 minutes total

Non-operating random

Frequency (Hz)	Slope (dB/octave)	PSD (g^2/Hz)
10–20	—	0.05
20–150	-3.0	—
150	—	0.0065

Total RMS acceleration: 1.6 g; test duration: 30 minutes x 3 axes

Non-operating swept sine

Frequency (Hz)	Amplitude
10–57	±.15 mm
57–150	2 g

Test duration: 4 sweeps per axis x 3 axes; each sweep: 10-150-10 Hz cycle at a sweep rate of 1 oct/minute

Bump	Half-sine, 15 g peak, 6 ms, 1000 hits (vertical with the device in its normal mounting position)
Free fall	IEC 68-2-32 free fall. Once on each face, total 6 faces (excluding bedrail hook) • 40 cm (16 in) without cradle and side carry bags • 75 cm (29.5 in) with cradle and side carry bags
Water and solids ingress resistance	Meets ingress protection level IP54 – protected against dust limited ingress (no harmful deposits) and against water sprayed from all directions (limited ingress permitted)
EMC	Complies with the requirements of standard IEC 60601-1-2:2014/EN 60601-1-2: 2015 and IEC 60601-1-2: 2007/EN60601-1-2:2007
Transient operating conditions	The DFM100 meets all specifications for 20 minutes during transient operating conditions of a temperature range of -20°C to 50°C and a relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa
Safety	Meets EN 60601-2-4:2011/GB9706.8-2009, EN60601-1/A1:2013/GB9706.1-2007
Other considerations	• The Efficia DFM100 is not suitable for use in the presence of concentrated oxygen or a flammable anesthetic mixture with air, oxygen or nitrous oxide • Hazards arising from software errors were minimized by the product's compliance with the software requirements contained in IEC 62304
Mode of operation	Continuous
AC line powered	100–240 VAC, 50 or 60 Hz, 1–0.46 A, class I equipment
Battery powered	Minimum 14.4 V, rechargeable lithium ion

Hazardous waste	Pb*	Hg	Cd	Cr6+	PBB	PBDE
	●	○	○	○	○	○

● = more than one of the device's raw materials contains this harmful substances and concentration over the standard concentration limit

○ = all the raw material concentrations of the device are within allowed limits

*Internal component(s) of the device may contain a level of lead in solder allowed to be present in portable emergency defibrillators under RoHs exemption Annex IV 17.

Electromagnetic capability

When using the Efficia DFM100, electromagnetic compatibility with surrounding devices should be assessed.

A medical device can either generate or receive electromagnetic disturbances. Testing for electromagnetic compatibility EMC with the appropriate accessories has been performed according to national and international standard for EMC for medical devices.

The EMC standards describe tests for both emitted and received disturbances. Emission tests deal with electromagnetic disturbances generated by the device being tested.

WARNING: Electromagnetic interference coming from other devices may degrade or obstruct the performance of the Efficia DFM100. The interference may come from signals radiated through the air or it may also come from signals conducted through wired connections such as power cords, patient connections or device-to-device connections such as ECG analog output. Electromagnetic compatibility with surrounding devices should be assessed prior to using the Efficia DFM100.

When connected to a patient, symptoms of interference may include degraded performance of ECG signals from pads or paddles or ECG lead sets, unexpected technical alarms, or critical failure status on the RFU indicator. Electromagnetic compatibility testing should include both radiated and conducted immunity. Testing in the presence of potentially interfering surrounding devices should assess typical Efficia DFM100 usage scenarios including powering on, monitoring and delivering therapy.

Fixed, portable and mobile radio frequency communications equipment could affect the performance of medical equipment.

Reducing electromagnetic interference

The Efficia DFM100 and associated accessories may be susceptible to interference from other RF energy sources and continuous, repetitive power line bursts. Examples of other sources of RF interference are medical devices, cellular products, information technology equipment and radio or television transmission. Should interference be encountered, as demonstrated by error conditions, artifact on the ECG or dramatic variations in parameter measurement values, attempt to locate the source.

Assess

- Is the interference intermittent or constant?
- Does the interference occur only in certain locations?
- Does the interference occur only when in close proximity to certain medical devices?
- Does the interference occur only when certain medical devices are turned on?
- Does the interference occur only when certain medical devices are connected to the same patient as the Efficia DFM100?
- Do parameter measurement values change dramatically when the AC line cord is unplugged?

Once the source is located, attempt to attenuate the EMC coupling path by distancing the monitor/defibrillator from the source as much as possible or by changing the location or routing of wired connections. If assistance is needed, call your local service representative.

Essential performance determinations

The following Essential Performance of the Efficia DFM100 was determined from the product's Safety Risk Assessment. This performance was maintained during EMC evaluation testing and disturbances per IEC 60601-1-2 and includes:

- The ability to deliver defibrillation therapy (manual, AED and synchronized cardioversion).
- The ability to deliver pacing therapy (fixed and demand).
- The ability to monitor the patient parameters (ECG monitoring, pulse oximetry, end-tidal CO_2, noninvasive blood pressure).
- The ability to detect and generate physiological alarms.

Restrictions for use

Artifacts on the ECG and parameter waveforms caused by electromagnetic disturbances should be evaluated by a physician or physician-authorized personnel to determine if it will negatively impact patient diagnosis or treatment.

Emissions and immunity

The Efficia DFM100 is designed and tested to comply with the radiated and conducted emissions requirements of international and national standards. The device is intended for use in the electromagnetic environments specified in the tables below. Given the electromagnetic emissions and immunity characteristics of the device, the customer or user should assure that the device is used within the specified environments. The EMC standards state that manufacturers of patient-coupled equipment must specify immunity and minimum separation distances between portable and mobile communications equipment.

See Table 1 through Table 4 for detailed information regarding declaration and guidance.

WARNING: The use of accessories, transducers and cables other than those specified might result in increased emissions or decreased immunity of the Efficia DFM100.

Immunity is defined in the standard as the ability of a system to perform without degradation in the presence of an electromagnetic disturbance. Degradation in ECG quality is a qualitative assessment which could be subjective.

Caution should be taken in comparing immunity levels of different devices. The criteria used for degradation is not specified by the standard and might vary with the manufacturer. Refer to the tables below.

Table 1: EMC emissions

Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1, Class B	Emergency medical services environment Professional healthcare facility environment
Harmonic emissions IEC 61000-3-2	Class A	Emergency medical services environment Professional healthcare facility environment
Voltage fluctuations and flicker emissions IEC 61000-3-3	Complies	Emergency medical services environment Professional healthcare facility environment

Table 2: Enclosure Ports

Immunity test	Immunity test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	±8 kV contact ±2, ±4, ±8, ±15 kV air	Emergency medical services environment Professional healthcare facility environment
Radiated RF electromagnetic field IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	Emergency medical services environment Professional healthcare facility environment
Radiated RF electromagnetic field IEC 60601-2-4 (see Para. 202.6.2.3)	20 V/m (only defibrillation) 80 MHz to 2.7 GHz	20 V/m (only defibrillation) 80 MHz to 2.7 GHz	Emergency medical services environment Professional healthcare facility environment
Proximity fields from RF wireless communications equipment IEC 61000-4-3	Refer to Table 3 on page 14	Refer to Table 3 on page 14	Emergency medical services environment Professional healthcare facility environment
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Emergency medical services environment Professional healthcare facility environment

Table 3: Proximity fields from RF wireless communications

Test frequency (MHz)	Band[a] (MHz)	Serivce[a]	Modulation[b]	Modulation[b] (W)	Distance (m)	Immunity level (V/m)
385	380–390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430–470	GMRS 460, FRS 460	FM ±5 kHz deviation 1 kHz sine	2	0.3	28
710 745 780	704–787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
810 870 930	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
1720 1845 1970	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400–2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240 5500 5785	5100–5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

WARNING: The use of portable and mobile radio communications equipment can affect the operation of this device. Keep all portable and mobile radio communications equipment at a minimum distance of 30 cm (12 inches) from any part of the Efficia DFM100.

Table 4: Input AC power ports

Immunity test	Immunity test level	Compliance level	Electromagnetic environment – guidance
Electrical fast transient and burst IEC 61000-4-4	±2 kV	±2 kV	Emergency medical services environment Professional healthcare facility environment
Surge, line to line IEC 61000-4-5	±0.5 kV, ±1 kV	±0.5 kV, ±1 kV	Emergency medical services environment Professional healthcare facility environment
Surge, line to ground IEC 61000-4-5	±0.5 kV, ±1 kV, ±2 kV	±0.5 kV, ±1 kV, ±2 kV	Emergency medical services environment Professional healthcare facility environment
Conducted disturbances induced by RF fields	3 V 0.15–80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	3 V 0.15–80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	Emergency medical services environment Professional healthcare facility environment
Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0°	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315° 0% UT; 1 cycle and 70% UT; 25/30 cycles Single phase: at 0°	Emergency medical services environment Professional healthcare facility environment
Voltage interruptions IEC 61000-4-11	0% UT; 250/300 cycle	0% UT; 250/300 cycle	Emergency medical services environment Professional healthcare facility environment

Table 5: Signal input and output ports

Immunity test	Immunity test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	±8 kV contact ±2, ±4, ±8, ±15 kV air	Emergency medical services environment Professional healthcare facility environment
Electrical fast transient and burst IEC 61000-4-4	±1 kV	±1 kV	Emergency medical services environment Professional healthcare facility environment
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15–80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	3 V 0.15–80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	Emergency medical services environment Professional healthcare facility environment

Table 6: Patient coupling ports

Immunity test	Immunity test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV air	±8 kV contact ±2, ±4, ±8, ±15 kV air	Emergency medical services environment Professional healthcare facility environment
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15–80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	3 V 0.15–80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz	Emergency medical services environment Professional healthcare facility environment

The EMC standards state that manufacturers of medical equipment must specify the maximum lengths of any associated cables that are likely to affect the compliance of the device with emission and immunity tests. The following table lists the maximum lengths of these cables.

Table 6: Applicable cables with maximum lengths

Part number	Maximum cable length	Description
3-lead ECG cable set		
M1669A	2.7 m	3-lead trunk cable, AAMI/IEC
M1674A	1.0 m	3-lead ICU snap, IEC
M1678A	1.0 m	3-lead set OR grabber, IEC
M1672A	1.0 m	3-lead set ICU grabber, IEC
M1673A	1.0 m	3-lead set ICU snap, AAMI
M1671A	1.0 m	3-lead set ICU grabber, AAMI
989803160641	2.7 m	Efficia 3/5 ECG trunk cable, AAMI/IEC
989803160651	1.0 m	Efficia 3-lead grabber, AAMI
989803160661	1.0 m	Efficia 3-lead grabber, IEC
989803170171	2.7 m	OR 3-lead ECG trunk cable, AAMI/IEC

Table 6: Applicable cables with maximum lengths (continued)

Part number	Maximum cable length	Description
5-lead ECG cable set		
M1645A	1.6 m	5-lead ICU snap, IEC
M1668A	2.7 m	5-lead ECG trunk cable, AAMI/IEC
M1971A	1.6 m	5-lead set, ICU grabber, IEC
M1974A	1.6 m	5-lead set, OR grabber, IEC
M1644A	1.6 m	5-lead set, ICU snap limb, AAMI
M1968A	1.6 m	5-lead set, ICU grabber limb, AAMI
989803160691	1.6 m	Efficia 5-lead grabber limb, AAMI
989803160701	1.6 m	Efficia 5-lead grabber limb, IEC
989803170181	2.7 m	OR 5-lead ECG trunk cable, AAMI/IEC
989803176161	1.6 m	5-lead snap limb, shielded, AAMI
989803176181	1.6 m	5-lead snap limb, shielded, IEC
Internal paddles		
M4741A	3.9 m	7.5 cm switched internal paddles
M4742A	3.9 m	6.0 cm switched internal paddles
M4743A	3.9 m	4.5 cm switched internal paddles
M1741A	3.9 m	7.5 cm internal paddles
M1742A	3.9 m	6.0 cm internal paddles
M1743A	3.9 m	4.5 cm internal paddles
M4740A	0.3 m	Internal paddles adapter cable
External paddles		
M3543A	4.8 m	External paddles – water resistant
989803196431	4.8 m	Efficia external paddles with PCI – water resistant
Hands-free pads therapy cables		
M3508A	2.2 m	HeartStart hands-free cable
989803197111	2.1 m	DFM100 pads cable
Multifunction defibrillator pads – barrel connector		
M3501A	0.6 m	Adult/child multifunction defibrillation electrode pads (10 sets)
M3504A	0.6 m	Infant multifunction defibrillation electrode pads (<10 kg) (5 sets)

Table 6: Applicable cables with maximum lengths (continued)

Part number	Maximum cable length	Description
Multifunction defibrillator pads – plug connector		
M3713A	1.2 m	HeartStart Pads Adult/Child (>10 kg) plus (10 sets)
M3716A	1.2 m	HeartStart Pads Adult/Child radiolucent multifunction electrode pads (10 sets)
M3717A	0.6 m	HeartStart Pads Infant (<10 kg) plus (5 sets)
M3718A	1.2 m	HeartStart Pads Adult/Child radiotransparent multifunction pads (10 sets)
M3719A	0.6 m	HeartStart Pads Infant (<10 kg) radiotransparent multifunction pads (5 sets)
989803158211	1.2 m	HS FR/FR2 defibrillator pads (1 set)
989803158221	1.2 m	HS FR/FR2 defibrillator pads (5 sets)
989803139261	1.2 m	SMART Pads II (1 set)
989803149981	1.2 m	SMART Pads III (1 set)
989803149991	1.2 m	SMART Pads III (5 sets)
$EtCO_2$ mainstream sensor		
M2501A	2.9 m	Mainstream CO_2 sensor
$EtCO_2$ sidestream sensor		
M2741A	1.0 m	Sidestream CO_2 sensor
SpO_2 sensors and cables		
M1191B	2.0 m	Adult reusable SpO_2 sensor, 2 m
M1191BL	3.0 m	Adult reusable SpO_2 sensor, 3 m
M1192A	1.5 m	Pediatric and small adult finger reusable SpO_2 sensor, 1.5 m
M1196A	3.0 m	Adult reusable SpO_2 clip sensor, 3 m
M1196S	2.0 m	Adult reusable clip SpO_2 sensor, 2 m
M1941A	2.0 m	SpO_2 extension cable, 2 m

Table 7: Electromagnetic immunity – life supporting systems

Immunity test	Test level	Compliance level	Electromagnetic environment – guidance
			Portable and mobile RF communications equipment should be used no closer to any part of the Efficia DFM100, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6/GB/T17626.6	3 Vrms 150 kHz to 80 MHz outside ISM bands[a]	3 Vrms	Recommended separation distance $d = 1.2\sqrt{P}$
	10 Vrms 150 kHz to 80 MHz in ISM bands	10 Vrms	
Radiated RF IEC 61000-4-3/GB/T17626.3	3 V/m 80 MHz to 2.5 GHz 10 V/m 80 MHz to 2.5 GHz 20 V/m (only SpO_2, CO_2, defibrillation) 80 MHz to 2.5 GHz	3 V/m* 10 V/m, 20 V/m** 80 MHz to 2.5 GH	Recommended separation distances $d = 1.2\sqrt{P}$ 80–800 MHz $d = 2.3\sqrt{P}$ 800 MHz–2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter's specified output power and *d* is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[c] should be less than the compliance level in each frequency range.[d] Interference might occur in the vicinity of equipment marked with the following symbol: 

* Applies to functions that are not considered life-supporting.

** No inadvertent energy delivery (per IEC 60601-2-4/GB9706.8, ISO 80601-2-61/YY0784). At 80 MHz and 800 MHz, the higher frequency range applies. These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Recommended separation distances

The Efficia DFM100 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Efficia DFM100 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Efficia DFM100 as recommended below, according to the maximum output power of the communications equipment.

Table 8: Recommended separation distances

Rated maximum output power of transmitter (W)	150 kHZ to 800 MHz $d = 1.2\sqrt{P}$	800 MHz to 2.5 GHz $d = 2.3\sqrt{P}$
0.01	0.1 m	0.2 m
0.1	0.4 m	0.7 m
1	1.2 m	2.3 m
10	4 m	7 m
100	12 m	23 m

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be determined using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter's manufacturer.

At 80 MHz and 800 MHz, the higher frequency range applies.

These guidelines might not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Footnotes

[a] The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765–6.795 MHz; 13.553–13.567 MHz and 26.957–27.283 MHz; and 40.66–40.70 MHz.

[b] The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80–2.5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.

[c] Field strengths from fixed transmitters, such as base stations for radio (cellular and cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Efficia DFM100 is used exceeds the applicable RF compliance level above, the Efficia DFM100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Efficia DFM100.

[d] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

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