

VIDACARE® EZ-IO® G3 POWER DRIVER

DESCRIPTION:

The Vidacare EZ-IO G3 Power Driver is a sealed, hand-held, lithium-battery powered medical drill. G3 Power Drivers are capable of producing a minimum of 500 human insertions. G3 Power Driver battery life expectancy may be dependent on actual usage (*bone density & average insertion time*), storage and frequency of testing. The G3 Power Driver is intended for the controlled insertion of an intraosseous needle set into human bone.

STORAGE: The G3 Power Driver and accessories may be stored at temperatures between -20°C to 50°C (-4°F to 122°F). Shelf life for the G3 Power Driver is 10 years. When storing in the soft Vascular Access Pack (VAP) remove the trigger guard to prevent accidental activation of the G3 Power Driver.

CLEANING AND DISINFECTION OF THE VIDACARE® G3 POWER DRIVER

1. Maintain BSI or PPE precautions.
2. Wipe entire exterior surface of G3 Power Driver with soft, clean moistened cloth. (If supplied, detach, clean and soak lanyard and trigger guard.) Use soft bristled brush to remove any visible soil or debris, paying particular attention to crevices and seam.
3. Spray exterior surface of G3 Power Driver with the antimicrobial commonly used by your institution, making sure to follow the antimicrobial manufacturer's recommendations.
4. Gently wipe exterior surfaces with gauze pads until visible debris is removed.
5. Clean and manipulate trigger using cloth moistened with selected anti-microbial.
6. Using sterile swabs, moisten with selected anti-microbial solution, gently clean inside opening around metal drive shaft.
7. After cleaning, inspect to ensure no visible debris remains, and no damage has occurred to the driver.
8. Dry driver with a soft, clean cloth (re-attach lanyard and trigger guard) and return to appropriate location.

If your clinical environment requires sterilization the G3 Power Driver can be sterilized using the STERRAD 100S, NX Standard cycle, and 100NX Standard cycle. STERRAD® is a product of Advanced Sterilization Products, a Johnson and Johnson Company.

Do not immerse or use excessive amount of liquid when performing cleaning and disinfecting. In the unlikely event of a driver failure, remove the G3 Power Driver, grasp the needle set by hand and advance the needle set into the medullary space while twisting the needle set.

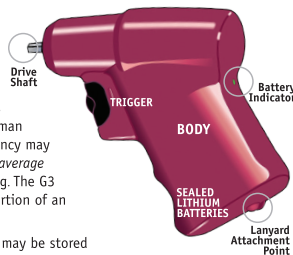
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CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.



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VIDACARE LIMITED EXPRESS WARRANTY AND DISCLAIMERS

(1) Warranty. Vidacare warrants to the original purchaser of the new products only ("Purchaser") that during the applicable warranty period: (a) the hardware Products will conform with Vidacare's written product specifications for such Products in all material respects for the shorter of (i) one year after shipment to Purchaser or (ii) the number of uses of such hardware Product as are specified by Vidacare, and (b) the Disposables will conform with Vidacare's written product specifications for such Products in all material respects until the expiration date designated therefore on such Disposables (collectively, the "Warranty Period"). The foregoing warranty shall not apply if the Products have been subjected to physical abuse, misuse, abnormal use, use not consistent with Vidacare's published directions and instructions for use, fraud, tampering, unusual physical stress, negligence or accidents. **(2) Limited Remedy; Warranty Procedure.** If a Product fails to conform to the warranty set forth under Section (1) above, Vidacare agrees to, in its discretion, repair, replace or refund the purchase price to Purchaser for the nonconforming Product. If a Product fails to conform to the warranty set forth under Section (1), Purchaser shall return the nonconforming Product to Vidacare during the applicable Warranty Period, at Purchaser's expense; provided, however that Purchaser shall first give prompt written notice to Vidacare, at which time Vidacare shall issue a Return Material Authorization ("RMA") number for the nonconforming Product. Products sent to Vidacare for warranty replacement without a valid RMA number displayed on the outside of the shipping container may, in Vidacare's discretion, be returned to Purchaser at Purchaser's expense. If a Product is returned in compliance with the foregoing requirements, Vidacare shall repair or replace the returned Product as soon as reasonably practicable at no additional cost to Purchaser if Vidacare has previously received payment for the returned Product or, at Vidacare's discretion, refund the purchase price. NOTWITHSTANDING ANYTHING TO THE CONTRARY IN THIS WARRANTY, THE REMEDIES PROVIDED UNDER THIS SECTION (1) SHALL BE PURCHASER'S SOLE AND EXCLUSIVE REMEDY FOR A FAILURE OF A PRODUCT TO CONFORM TO THE WARRANTY SET FORTH UNDER SECTION (1) ABOVE. **(3) Warranty Disclaimers.** TO THE MAXIMUM EXTENT PERMITTED BY APPLICABLE LAW, THE EXPRESS WARRANTY SET FORTH IN SECTION (1) IS THE SOLE AND EXCLUSIVE WARRANTY AND GIVEN IN LIEU OF ALL OTHER WARRANTIES, WHETHER EXPRESS, IMPLIED OR STATUTORY, INCLUDING WITHOUT LIMITATION THE IMPLIED WARRANTIES OF MERCHANTABILITY, NON-INFRINGEMENT, FITNESS FOR A PARTICULAR PURPOSE, SATISFACTORY QUALITY OR SUITABILITY. IF THE DISCLAIMER OF ANY IMPLIED WARRANTY IS NOT PERMITTED BY APPLICABLE LAW, THE DURATION AND SCOPE OF SUCH WARRANTY IS LIMITED TO NINETY (90) DAYS FROM THE DATE OF ORIGINAL PURCHASE. OTHER THAN AS WARRANTED UNDER SECTION (1), THE PRODUCTS ARE PROVIDED "AS IS." THE PRODUCTS ARE DESIGNED FOR USE SOLELY BY TRAINED AND LICENSED MEDICAL PERSONNEL USING REASONABLE MEDICAL DISCRETION IN EMERGENCY MEDICAL SITUATIONS OR MEDICALLY NECESSARY SITUATIONS. VIDACARE DISCLAIMS ANY AND ALL LIABILITY WITH RESPECT TO THE PRODUCTS ARISING FROM ANY USE OF THE PRODUCTS THAT IS NOT CONSISTENT WITH VIDACARE'S PUBLISHED DIRECTIONS AND INSTRUCTIONS FOR USE. **(4) Limitation of Liability.** IN NO EVENT SHALL VIDACARE BE LIABLE TO PURCHASER, ANY CUSTOMER OR ANY OTHER THIRD PARTY IN ANY MANNER FOR ANY SPECIAL, NON-COMPENSATORY, CONSEQUENTIAL, INDIRECT, INCIDENTAL, STATUTORY OR PUNITIVE DAMAGES OF ANY KIND, INCLUDING, WITHOUT LIMITATION, FOR LOST PROFITS, LOST SALES, LOST REVENUE OR LOSS OF USE, REGARDLESS OF THE FORM OF ACTION, WHETHER IN CONTRACT, TORT, NEGLIGENCE, STRICT PRODUCTS LIABILITY, OR OTHERWISE, EVEN IF VIDACARE HAS BEEN INFORMED OF OR IS AWARE OF THE POSSIBILITY OF ANY SUCH DAMAGES IN ADVANCE. VIDACARE'S TOTAL AGGREGATE LIABILITY IN CONNECTION WITH THIS AGREEMENT OR THE PRODUCTS SHALL BE LIMITED TO THE SUM OF THE AMOUNTS PAID TO REPRESENTATIVE BY VIDACARE DURING THE TWELVE (12) MONTHS IMMEDIATELY PRECEDING THE DATE OF THE EVENT GIVING RISE TO A CLAIM AGAINST VIDACARE.

G3 POWER DRIVER



Directions for Use

Immediate Vascular Access...
When You Need It.SM

Vidacare.com

vidacare
4350 Lockhill Selma Road, Suite 150, Shavano Park, Texas 78249, U.S.A.
866-479-8500 Vidacare.com

Vidacare Declaration Electromagnetic Emissions

The G3 Power Driver is intended for use in the electromagnetic environment specified below. The customer or the user of the Vidacare Driver should assure that it is issued in such an environment.

Emission Test	Compliance	Compliance
RF Emissions CISPR 11	Group 1	The G3 Power Driver uses RF energy only for its internal function. Therefore, its RF Emissions are very low and are not likely to cause interference in nearby electronic equipment.
RF Emissions CISPR 11	Class B	The G3 Power Driver is suitable for use in all establishments, including domestic establishments and those directly connected to the public low voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Not applicable	

Vidcare's Declarations – Electromagnetic Immunity


The G3 Power Driver is intended for use in the electromagnetic environment specified below. The customer or the user of the Vidacare Driver should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment — guidance
Electrostatic discharge (ESD) IEC 61000-4-2	+/- 6 kV Contact +/- 8 kV air	+/- 6 kV Contact +/- 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material the relative humidity should be at least 30%
Electrical fast Transient/burst IEC 61000-4-4	+/- 2 kV for power supply lines +/- 1 kV for input/output lines	Not applicable (battery powered) Not applicable (no I/O lines)	Mains power quality should be that of a typical commercial or hospital environment
Surge IEC 61000-4-5	+/- 1 kV differential mode +/- 2 kV common mode	Not applicable (battery powered)	Mains power quality should be that of a typical commercial or hospital environment
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% Ur (>95% dip in Ur) for 0.5 cycles 40% Ur (60% dip in Ur) for 5 cycles 70% Ur (30% dip in Ur) for 25 cycles <5% Ur (95% dip in Ur) for 5 sec	Not applicable (battery powered)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the G3 Power Driver requires continued operation during power mains interruptions, it is recommended that the Power Driver be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of typical location in typical

NOTE Ur is the a.c. mains voltage prior to application of the test level.

Guidance and Manufacturer's Declaration — Electromagnetic Immunity

The G3 Power Driver is intended for use in the electromagnetic environment specified below. The customer or the user of the G3 Power Driver should assure that it is used in such an environment.

Immunity test	IEC 60601 test level	Compliance Level	Electromagnetic environment — guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	Not applicable (battery powered)	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Power Driver including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.</p> <p>Recommended separation distance</p> $d = \left[\frac{3.5}{V_t} \right] \sqrt{P}$ $d = \left[\frac{3.5}{E_t} \right] \sqrt{P}$ $d = \left[\frac{7}{E_t} \right] \sqrt{P}$ <p>Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).</p> <p>Field strengths from fixed RF transmitters as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.b</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol: </p>
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	
<p>NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.</p> <p>NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</p> <p>a Field strengths from fixed transmitters, such as base stations for radio (cellular/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 G3 Power Driver is used exceeds the applicable RF compliance level above, the G3 Power Driver should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the G3 Power Driver.</p> <p>b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.</p>			

Recommended separation distances between portable and mobile RF communications equipment and the [EQUIPMENT or SYSTEM]

The G3 Power Driver is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the G3 Power Driver can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the EZ-IO Power Driver recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = \left[\frac{3.5}{V_t} \right] \sqrt{P}$	80 MHz to 800 MHz $d = \left[\frac{3.5}{E_t} \right] \sqrt{P}$	800 MHz to 2.5 GHz $d = \left[\frac{7}{E_t} \right] \sqrt{P}$
.01	0.12	0.12	0.23
.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated 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 manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Medical Electrical Equipment needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in this manual.

Portable and mobile RF communications equipment can affect Medical Electrical Equipment.

The use of Accessories, transducers and cables other than those specified by the manufacturer, may result in increased Emissions or decreased Immunity of the Power Driver.

The G3 Power Driver should be observed to verify normal operation in the configuration in which it will be used.

The G3 Power Driver is designed and tested to run intermittently with a duty cycle of 30 seconds on 1 minute off cycle.

Equipment Classification

Type of protection against electric shock	NA Internal powered equipment
Degree of protection against electric shock	Type BF applied part
Degree of protection against ingress of water	IPX0 or ordinary protection
Degree of safety or application in the presence of a flammable anesthetic mixture	Equipment not suitable for use in the presence of a flammable anesthetic Mixture with air or with oxygen or nitrous oxide
Mode of operation	Continuous



At the completion of the G3 Power Driver's service life, proper disposal is the responsibility of the institution or service (directive 2002/96/EC).



Degree of protection against electric shock BF Applied part.