Date: - 28<sup>th</sup> January, 2019

# Corrigendum

### For

# Electro Thermal Bipolar Tissue Sealing System for the Department of Surgical Gastroenterology

NIT Issue Date : 01<sup>st</sup> November, 2018

NIT No. : Admn/Tender/130/2018-AIIMS.JDH

Pre-Bid Meeting : 14<sup>th</sup> November, 2018 at 05:00 PM

Earlier Last Date of Submission : 30<sup>th</sup> January, 2019 at 03:00 PM

Extended Last Date of Submission: 14th February, 2019 at 03:00 PM

Bid opening : 15<sup>th</sup> February, 2019 at 03:15 P.M

The following revised and additional specification will be added:-

# 1. Page No. 11, Subheading: Generator specification, Bullet no. 2, 3, 4, 5, 6, 7, 8, 9, 10, 11: For

- The RF generator should confirm to all safely standards including IEC 60601-1, IEC 60601-2-2:2006 Clause 44.3 and IEC 60601-2-2:2009 Clause 201.11.6.3, IEC 60601-1:1988 + A1:1991 + A2:1995 clause 49, IEC 60601-1:2005 clause 11.8, IEC 60601-2-2:2006 clause 51.101, and IEC 60601-2-2:2009 clause 201.11.8, IEC 60601-1-2and IEC 60601-2-2.
- ESD Immunity (IEC 60601-1-2 Sub-Clause 36.202 and IEC 61000-4-2)
- Radiated Immunity (IEC 60601-1-2 sub-clause 36.202.2 and IEC 61000-4-3)
- Electrical Fast Transient/Burst (IEC 60601-1-2 sub-clause 36.202.3.1 and IEC 61000-4-4)
- Surge Immunity (IEC 60601-1-2 sub-clause 36.202.3.2 and IEC 61000-4-5)
- Emissions (IEC 60601-1-2 sub-clause 36.201.1, IEC 60601-2-2 sub-clause 36 and CISPR 11 Class A).
- Harmonic distortion (IEC 60601-1-2 sub-clause 36.201.3.1 and IEC 61000-3-2)
- Conducted disturbances (IEC 60601-1-2 sub-clause 36.202.6 and IEC 61000-4-6)
- Power frequency magnetic fields (IEC 60601-1-2 sub-clause 36.202.8.1 and IEC 61000-4-8).
- Voltage dips, short interruptions and variations (IEC 60601-1-2 sub-clause 36.202.7 and IEC 61000-4-11)

#### Read as:

- a) An integrated system with 300W output generator and a single touch screen for Monopolar, Bi-polar and Vessel fusion integrated in one generator or it had only vessel fusion in one generator.
- b) The RF generator should confirm to all safely standards including ESD Immunity, Radiated Immunity, Electrical Fast Transient/Burst, Surge Immunity, Emissions, Harmonic distortion, Conducted disturbances, Power frequency magnetic fields and Voltage dips, short interruptions and variations of International standard with IEC 60601-1, 60601-1-2 and 60601-2-2 certificate.

## 2. Page No. 11, Subheading- "Accessories", Bullet no. 1, 2, 3, 4, 5:

Open & laparoscopic 10mm and 5mm seal and cut instrument with hand switch activation capability.

- Vessel sealing instrument for open surgeries with instrument length between 18-19cm and electrode length between 16-17cm, having 28 degree curved jaw with contoured tip for blunt dissection and having activation both through hand activation and foot activation with a manually controlled cutting mechanism.
- 36mm jaw length, 180 degree rotatable instrument with curved blade for large volume tissue. Should have the manual cutting mechanism.
- Vessel sealing instrument for open surgeries with length between 16-18cm, 180 degree shaft rotations, with 12-14 degree jaw curve.
- 5mm multifunctional laparoscopic device for tissue fusion and dissection.

#### Read

Open & laparoscopic 10mm and 5mm seal and cut instrument with hand switch activation capability.

#### Open:

- a) Vessel sealing instrument for open surgeries with instrument length between 18-19cm and electrode length between 16-17cm, having 28 degree curved jaw with contoured tip for blunt dissection and having activation both through hand activation and foot activation with a manually controlled cutting mechanism Quantity 2
- b) 36mm jaw length, 180 degree rotatable instrument with curved blade for large volume tissue. Should have the manual cutting mechanism- Quantity 1
- c) Vessel sealing instrument for open surgeries with length 23cm, 180 degree shaft rotations, with 12-14 degree jaw curve- Quantity 1

#### Laparoscopic:

- a) 5mm multifunctional laparoscopic device for tissue fusion and dissection, length of 37cm- Quantity 2.
- b) 10mm multifunctional laparoscopic device for tissue fusion and dissection, length of 37cm- Quantity 1.
- c) 5mm multifunctional laparoscopic device for tissue fusion and dissection, length of 44cm- Quantity 1.
- **3.** Technical qualification will include successful demonstration of the item.