Electronic Signature Information

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Title	Work Instruction for Gradient Cable Tool Kit
Reason For Change	Adding orange die #50 for 3/0 AWG lug and associated pin gage
Originator	212473777_brian__gracyalny
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Route	Signer	Function	Status	Comments	Completion Date
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Periodic Review

There are no signatures or routes related to this business object.

Obsolescence Approval

There are no signatures or routes related to this business object.

* Printed versions are For Reference Only *
+ Indicates a task was reassigned from an original assignee

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GE Healthcare

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DOC2104279 Work Instruction for Gradient Cable Tool Kit

Applicable to ISO 13485 QMS

TECHNICAL BULLETIN

Technical Bulletin Unique Identifier	DOC2104279 Rev 3
Title	Work Instruction for Gradient Cable Tool Kit
Subject	Calibration / Inspection work instruction for GEHC 5790054
Applicability (e.g., affected product, process)	MR450, MR450W, MR450W GEM, Artist, MR750, MR750W, Architect, Voyager, Pioneer
Date	20-Apr-2022
Originating Business (select one)	☐ **GEHC Digital** (Imaging and Care Area Solutions, Value Based Care) ☐ **Clinical Care Solutions** (Ultrasound, Lifecare Solutions) ☒ **Imaging** (Magnetic Resonance, Molecular Imaging and Computed Tomography, X-ray, Interventional, Surgery, Womens Health, Global Services) ☐ **Other**: _____
Originating Modality	MR
Details	Gradient Cable Tool Kit Inspection
Tracking Number	NA – informational only
Affected Service Publications	Discovery MR450 and MR750 System Installation Optima MR450W, MR450W GEM, and Signa Artist System Installation Discovery MR750W GEM and Signa Architect System Installation Signa Pioneer 3.0T, Signa Voyager 1.5T, Signa Hero System Installation
Resolution	See below
Technical Bulletin POC	B. Gracyalny GEHC MR Engineering 212473777

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DOC2104279 Work Instruction for Gradient Cable Tool Kit

Applicable to ISO 13485 QMS

1. **Gradient Cable Tool Kit 5790054**

   Calibration Interval: 12 months

   Justification: Certified crimps are a safety requirement for termination to the bus bar, PGR cabinet and secondary pen wall connections to the gradient filter. Inspection of gradient cable crimper, 5790056, will require periodic replacement of compression dies numbers 50, 45, 42, 37, and 24 and handle spread calibration due to use wear-out.

GEHC Part Number	Description
5790056	Thomas & Betts Crimper model TBM5-S
5790057	Greenlee Cable Cutter model 45207
5790059	Greenlee Insulation Stripper model 1903
5790061	Greenlee 1903 Replacement Blades part number 13544
5790062	Bausch & Lomb 10x Magnification Inspection model 81-41-70
5790064	Laminated Gradient Cable Tool Kit Instructions
5790053	Hard Shell, Sealed, Latched Flight Case with handle, wheels, and customer foam

Table 1: 5790054 Gradient Tool Kit Components

At these intervals, the Gradient Cable Tool Kit needs to be inspected to assure all tools are in the kit (if missing - replaced) and the crimper follows the work instruction below.

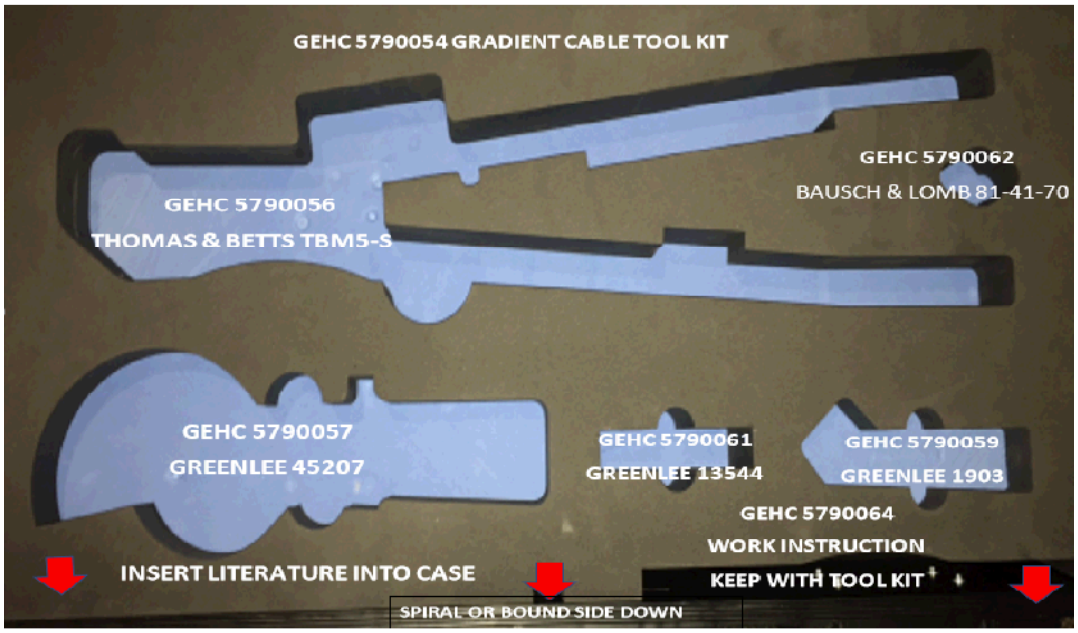


Illustration 1: Location of tools in gradient cable tool kit

2. Inspection / Calibration Work Instruction

a. Visual Inspection: Tool must be free of cracks, sharp edges, and other obvious imperfections that may affect the performance of the tool. Nest area must be free of burrs, dents, or scratches.

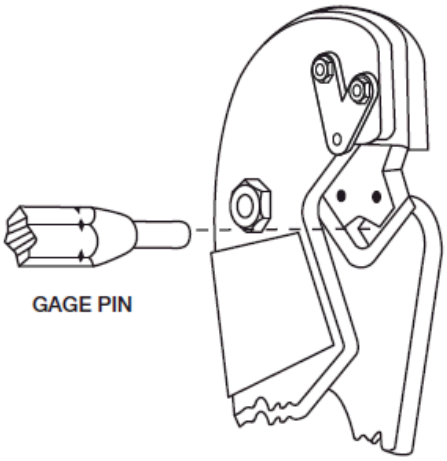
b. Gaging Procedure: This procedure should be done at qualified calibration facility. The tools required are pin gages (2) per AWG crimp (color specified below). An example of dies required are listed in Table 3 below.

a. Wipe dies before gaging, insert die nest into tool (this is done for all 4 dies).

b. Squeeze handles until jaws are fully closed.

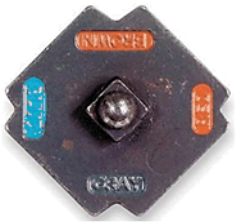
c. Select minimum and maximum pin gage (from table below), insert it into nest with minimal hand pressure, limit should fall between the min./max. range.

d. If the die opening is larger than the maximum pin gage, it must be replaced (see die catalog numbers in Table 2).



Die Nest inserted into crimper tool

Die PN: 13454 **Die PN: 13455**



Die Color	Die Catalog Number	Gaging Min. – Max. (inch)
Blue (#24) 6 AWG	13454	0.181 – 0.201
Green (#37) 1 AWG	13455	0.313 – 0.335
Pink (#42) 1/0 AWG	13455	0.351 – 0.371
Black (#45) 2/0 AWG	13455	0.383 – 0.406
Orange (#50) 3/0 AWG	13455	0.429 – 0.454

Table 2: Dies used for gradient cables

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DOC2104279 Work Instruction for Gradient Cable Tool Kit

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3. **Additional tools required for the inspection/calibration:** The following is the list of additional tools that should be purchased locally that are needed to perform the inspection/calibration.

   Required tool for calibration: Vermont gages (or equivalent):

Die Catalog Number	Die Color	Diameter Minimum (inch)	Vermont Gage Part Number (or equivalent)	Diameter Maximum (inch)	Vermont Gage Part Number (or equivalent)
13454	Blue	0.181	6DCG6	0.201	6DCJ3
13455	Green	0.313	6DCY2	0.335	6DDA4
13455	Pink	0.351	6DDD0	0.371	6DDF0
13455	Black	0.383	6DDG1	0.406	6DDJ4
13455	Orange	0.429	6DDL7	0.454	6DDR2

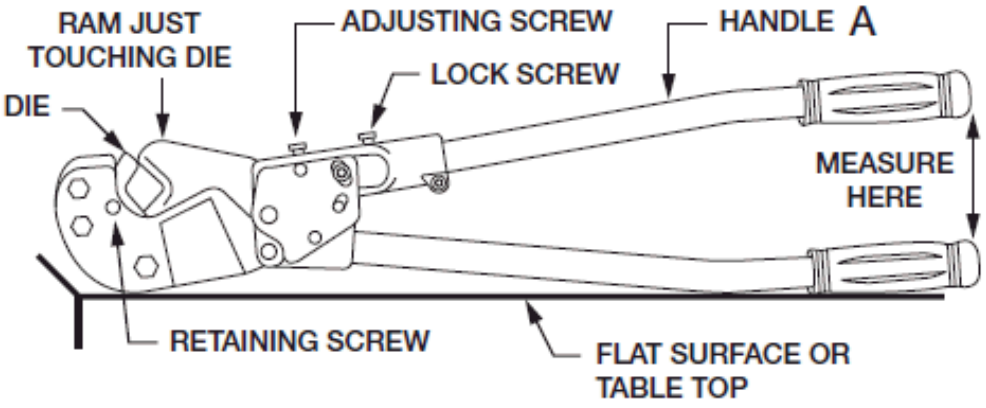
Table 3: Required pin gages needed for gradient crimper calibration

4. **Handle Spread Inspection:** This test will ensure the tool produces a reliable compression and adjusts the handle spread.

   a. Insert die in place

   b. Lay tool on a flat surface—open handle A (below) and allow it to close under its own weight, i.e., guide the tool until the handle has resistance, the ram should be touching the die.

   c. Measure the distance between the handle grips. In a properly adjusted tool, the distance should be between 11 in. and 14 in., if less than 11 in. or more than 14 in. the tool needs adjustment.



5. Handle Spread Adjustment:

1. Loosen the lock screw.
2. To increase the distance between the handles, turn the adjustment screw clockwise.
3. To decrease the distance between the handles, turn adjustment screw counterclockwise.
4. Tighten the lock screw.
5. Recheck handle distance and adjust again if necessary.

Rev	Page	Description of Content Changed	Reason for Change or Change Control Number	Author Name / SSO	Date
1	All	Initial Entry	Initial Entry	B. Gracyalny 212473777	01-Mar-2018
2	Pg. 4	Table 3	Corrected max diameter of Blue Die	B. Gracyalny	16-Aug-2018
3	Pg. 2,4	Section 1, 2, 3	Added orange die #50 for 3/0 AWG lug and associated pin gage	B. Gracyalny 212473777	20-Apr-2022