	Calibration Assembly Procedure	
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Calibration Assembly Procedure

CHANGE HISTORY		
Revision	Description of Change	Effective Date
1	Initial Release at ECR 000322-02	

APPROVALS		
Reviewer's Title		Date
Director of Research & Development	Deborah Urbanek	/ /
Director of Operations	Alan Runck	/ /
Director of Regulatory Affairs/QA	Joyce Brendle	/ /
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1.0 PURPOSE

This document describes the procedures that must be followed when assembling calibration assemblies for ACME handpieces.

2.0 SCOPE

Calibration assemblies must be assembled as described in this document.

3.0 RESPONSIBILITIES

- Operations Technician: Perform the procedures and record information as described in this document.
- Director of Operations (or designee): Verify that the current version of this document correctly describes the procedures that are to be followed.

4.0 ASSOCIATED MATERIALS/DOCUMENTS

<u>Document/Part Number</u>	<u>Title</u>
102-002	Bin Card Procedure
102F-005	ACME Drill Assembly Process Tag
250-0100-0020	Carrier Plate
250-0100-0031	Serial No. Plate
280-0222-1187	Flat Head Screws
280-0256-2187	Datum Screws
280-0256-2250	Brace Screws
280-0286-2187	Allen Head Screws (2)
280-0286-4250	Carrier Right Screws
293-0100-0001	Nye Lubricant
294-0100-0242	Loctite #242
445-0100-0006	Right Housing Sub-Assembly
445-0100-0007	Left Housing Sub-Assembly
450-0100-0004	Trigger Assembly
450-0100-0009	Back Trigger Assembly
450-0100-0011	Carrier Assembly

5.0 TOOLS AND EQUIPMENT

1. 1/16" Allen key.
2. 7/64" Allen key.
3. Phillips head screw driver.

6.0 DEFINITIONS

None.

7.0 PROCEDURE

1. Generate a Bin Card for the assembly (see Procedure 102-002).
2. Clear the work area on the assembly floor.
3. Obtain the parts that are required. Record the date, issue quantity and balance remaining on the stock card when withdrawing parts.
4. On the Bin Card, record the revision level (if applicable) and the Purchase Order (PO) number or Stock Order (SO) number for the parts that were obtained.
5. Assemble calibration assemblies as described below:
 - a. Place a carrier assembly (Part No. 450-0100-0011) inside a right housing sub-assembly (Part No. 445-0100-0006).
 - b. Align the holes in the carrier assembly with the dowel pins inside the right housing sub-assembly and slide the manifold along the nipples until the manifold fits over the screw boss and cut-out in the housing (see Figure 1).

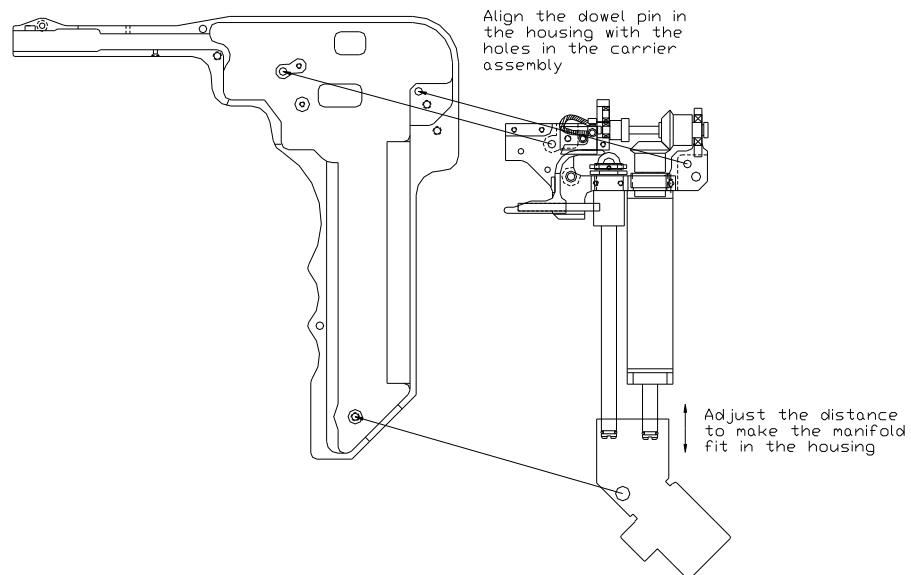


Figure 1.

- c. Secure the carrier assembly to the right housing sub-assembly using a datum screw (Part No. 280-0222-2187) and a carrier right screw (Part No. 280-0286-4250) (see Figure 2). Place a small amount of locktite in the threads of the screws before using them.
- d. Screw the brace screw (Part No. 280-0286-2250) into the power trigger brace (see Figure 3). Place a small amount of locktite in the threads of the screw before using it.
- e. Remove the Allen head screw located next to the screw brace. Apply locktite to the threads of the screw and then screw it back.

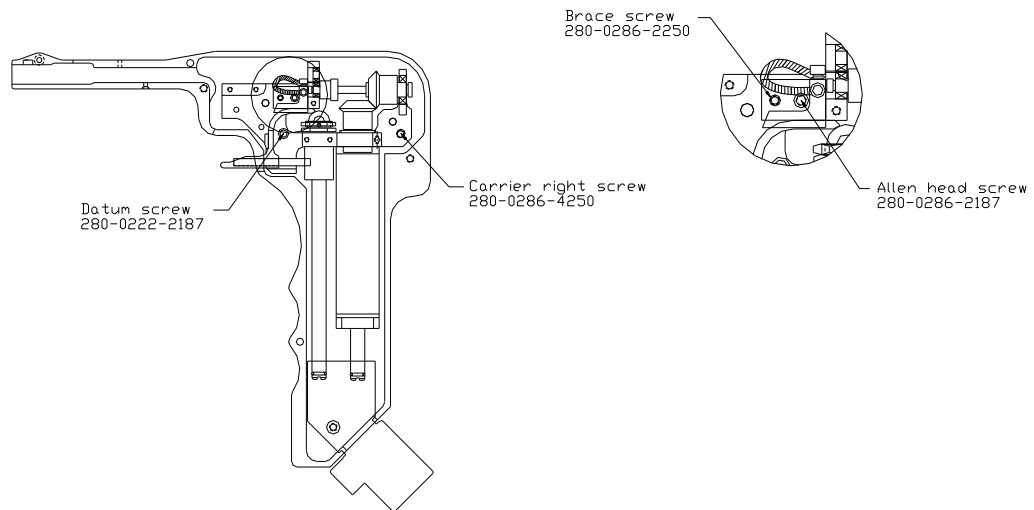


Figure 2.

Figure 3.

- f. Slide the roller of the back trigger assembly (Part No. 450-0100-0009) under the back return of the trigger assembly (Part No. 450-100-0004) (see Figure 4).



Figure 4.

- g. Slide the back trigger assembly and trigger assembly over the dowel pins of the carrier. Wrap the back trigger spring over the back trigger assembly (see Figure 5).
- h. Position the trigger assembly so that it is between the housing and the power trigger.

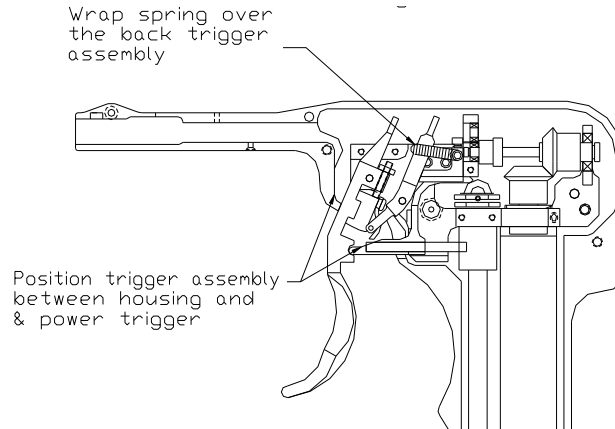


Figure 5.

- i. Position a carrier plate (Part No. 250-0100-0020) over the dowel pins of the carrier and the L-block. Use two Allen head screws to secure the carrier plate (see Figure 6).
- j. Fasten a serial number plate (Part No. 250-0100-0020) to the bottom of the housing using a flat head screw (Part No. 280-0222-1187). The serial number on the serial number plate is assigned to the handpiece.
- k. Record the Serial Number of the handpiece on the ACME Drill Assembly Process Tag.
- l. Place the completed calibration assembly and the ACME Drill Assembly Process Tag in the area for inspection.

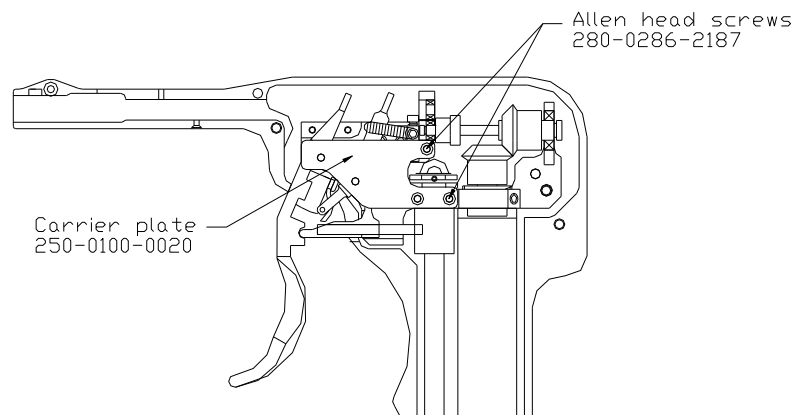


Figure 6.

8.0 RECORDS

None.