

**Table: Medical Physicist Involvement in Equipment Adjustments, Changes, or Repairs**

For any adjustment, change, or repair not listed in the table below, or if the facility is unsure as to the full extent of the adjustment, change, or repair, the facility should consult their medical physicist to determine the proper extent of his or her involvement in evaluating the item.

<b>Item</b>	<b>Major Repair</b>	<b>Medical Physicist Involvement</b>
<b><u>Automatic Exposure Control</u></b>		
AEC replacement	Y	MP conducts evaluation in person
Thickness compensation internal* adjustment	N	MP oversight
AEC sensor replacement	Y	MP conducts evaluation in person
AEC circuit board replacement	Y	MP conducts evaluation in person
Density control – internal* adjustment	N	MP oversight
<b><u>Bucky (New to Facility) Replacement</u></b>		
AEC sensor also replaced	Y	MP conducts evaluation in person
AEC sensor not replaced	N	MP oversight
FFDM detector also replaced	Y	MP conducts evaluation in person
FFDM detector not replaced	N	MP oversight
<b><u>Filter replacement</u></b>		
Installation	Y	MP conducts evaluation in person
Reassembly	Y	MP conducts evaluation in person
<b><u>Manufacturer's software modifications</u></b> <i>(see approved alternative standard)</i>		
	Y	MP conducts evaluation in person
<b><u>FFDM detector replacement or repair</u></b>		
	Y	MP conducts evaluation in person
<b><u>FFDM Display (monitor)/Printer Replacement</u></b>		
	Check FFDM manufacturer's QC manual	Follow FFDM manufacturer's QC manual
<b><u>Collimator</u></b>		
Replacement	Y	MP conducts evaluation in person
Reassembly with blade replacement	Y	MP conducts evaluation in person
Adjustment	N	MP oversight
<b><u>Compression Device</u></b>		
Pressure adjustment	N	MP involvement optional
Thickness scale accuracy adjustment but only if it affects AEC performance	N	MP oversight
Repair of auto decompression	N	MP involvement optional

<b>Item</b>	<b>Major Repair</b>	<b>Medical Physicist Involvement</b>
<b><u>Compression Paddle</u></b>		
Paddle (new to facility) replacement	N	MP oversight
Deflection adjustment	N	MP oversight
Adjustment due to extension beyond allowable limit, or visibility on images	N	MP oversight
<b><u>X-ray Unit</u></b>		
kVp, mA or time internal* adjustments	N	MP oversight
High voltage generator replacement	Y	MP conducts evaluation in person
X-ray tube replacement	Y	MP conducts evaluation in person
<b><u>Darkroom</u></b>		
Repair of light leaks	N	MP involvement optional
Safe light change	N	MP involvement optional
<b><u>Film Type/Speed Change</u></b>		
	N	MP oversight
<b><u>Processor</u></b>		
Chemistry type change	N	MP involvement optional
Fixer/Developer replacement	N	MP involvement optional
Installation	Y	MP conducts evaluation in person
Reassembly	Y	MP conducts evaluation in person
Replenishment rate adjustment	N	MP involvement optional
Roller replacement	N	MP involvement optional
<b><u>Cassette Replacement</u></b>		
Same screen speed	N	MP involvement optional
Faster screen speed	N	MP oversight
Slower screen speed where the dose increase may exceed 3.0 mGy for the standard breast	Y	MP conducts evaluation in person

The above information can be found at the FDA's Policy Guidance Help System (PGHS) at:  
[https://www.accessdata.fda.gov/cdrh\\_docs/presentations/pghs/Polic\\_Guidance\\_Help\\_System.htm](https://www.accessdata.fda.gov/cdrh_docs/presentations/pghs/Polic_Guidance_Help_System.htm)

See Quality Assurance – Equipment, Mammography Equipment Evaluations, Question 10.