

Dear BAPO Members,

Recently, our members brought to our attention the perceived lack of clarity around the lifetime of Ottobock joints. BAPO reached out to Ottobock to work on providing a response to our members on this important issue.

Ottobock can confirm that the three-year lifetime of Ottobock joints is based on an average of three million cycles under dynamic load, which equates to approximately 5.5km per day over three years. Ottobock has advised that this information should be used to assess the lifetime of the joint for each patient, all of whom have different activity levels. Kevin Green, Head of Neuromobility & NHS Clinical Services for Ottobock, advises that it is a pre-requisite of the Medical Devices Regulations (2017/745) and UK MDR 2002 (Amendment) for manufacturers to state a lifetime for all componentry. However, the lifetime details should be used to help clinicians determine the safe use of the components and are not intended as a definitive lifetime of every joint in use.

Ottobock can confirm that the reason for no longer servicing joints is due to the closure of Ottobock Minworth, which is where UK customers would have previously returned their AFOs/KAFOs for servicing/repairs. To mitigate this issue, Ottobock has agreed to provide endorsed service training to manufacturers. Ottobock advises that their joints can continue to be used in line with the activity information provided above (the equivalent of 5.5km per day over a three-year period) as long as the joint has been serviced regularly, by a manufacturer who has been endorsed by Ottobock, in line with BAPO's Knee Ankle Foot Orthoses standard to ensure the safe maintenance and use of KAFOs.

Finally, Ottobock has agreed to deliver a suite of educational offerings to help train Orthotists to check for signs of stress on the joints.

BAPO are grateful for the positive stance Ottobock has taken on this situation and the collaborative nature of the conversations we have had. For any additional detail on the lifespan of Ottobock joints please visit Ottobock's MDR website:

<https://www.ottobock.com/en-gb/services/mdr-suite>, or email us: orthoticsuk@ottobock.com

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Chair, BAPO

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