
Urgent Field Safety Notice

Product Name: Steeper Select Myoelectric Hands – All Wrist Variants and sizes

Affected hand variants: All hands manufactured or repaired since February 2013

Dear Customer / Distributor,

As part of our Field Safety Corrective Action, this notification provides information that Hugh Steeper Ltd have received a single report that a Select Myoelectric hand has suffered an electronic failure whilst an end user was driving a motor vehicle.

As a result of this failure, Hugh Steeper have immediately updated the Technical and User information leaflets to include the following actions when driving to minimise any further risks to the end user.

These are available for download at the following address:

<https://www.steepergroup.com/prosthetics/upper-limb/hands/select-myoelectric/>

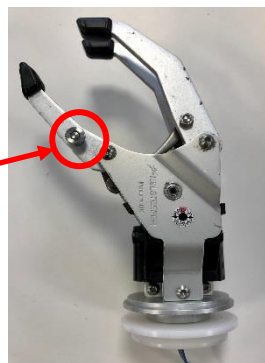
Description of Issue:

In the event of a major electronic malfunction on the hand or the end users prosthesis / socket whilst driving a motor vehicle or other activity, the end user will not be able to open the hand.

Identification of Issue:

Hands that have been built or repaired since February 2013. A quick and easy check through the inner hand shell / cosmesis can be performed on the thumb to feel for a mechanical release as per photograph below. If the thumb is solid, it will have been built or repaired since February 2013 and the required actions below must be implemented with immediate effect.

Location of mechanical thumb release
on hands built prior to February 2013



Affected hand serial numbers are in the table in Annex 1 at the end of this communication.

If in any doubt, please contact Customer Services at the following email address:

customerservices@steepergroup.com

REQUIRED ACTIONS:

1. Whilst using the device to drive a motor vehicle or other activities that could cause injury / harm to the end user when being used, they must open the Fingers and Thumb with sufficient gap to allow the hand to be removed from the activity it's being used for and then turn POWER OFF to the custom Prosthesis / Socket or the hand itself.

This will prevent the end user accidentally sending an electrode signal to the hand and closing the fingers and thumb. This will also prolong the battery life.

2. If the hand is closed fully and fails to open, the socket / prosthesis must be removed from the residual limb when safe to do so and then remove the hand from the Prosthesis.

Resolution:

Hugh Steeper Ltd are making a further improvement to the device by re-introducing a more effective thumb release mechanism. This will be introduced on all returned hands for repair and on all new build hands from the 1st May 2019.

Anyone wishing to return their hand to upgrade the Thumb, can do so by contacting Hugh Steeper Ltd Customer Services at customerservices@steepergroup.com and quoting RTA 9999.

A specific Steeper Select Myoelectric hand return form will be mailed through for completion. This must be sent through via post, email or fax using the details below, complete with the hand serial number, any previous sales order information and the postal address where the device is to be returned.

If the customer does not want to upgrade the thumb or the device is no longer in use. Please complete the disclaimer section at the end of the form and forward a copy using the details below so records can be updated.

Hugh Steeper Ltd Contact Information:

Customer Services – customerservices@steepergroup.com

Contact Reference Person: Lee Kempton

Telephone: +44 113 2704841

Fax: +44 113 2725689

Postal Address for Return:

RTA 9999

Prosthetic Returns Department

Hugh Steeper Ltd
Unit 3, Stourton Link,
Intermezzo Drive,
Leeds,
LS10 1DF,
West Yorkshire,
United Kingdom.

Questions and Answers:

1. Can the Select Myoelectric hand still be used with no mechanical thumb release?

YES, the end user risk is very low. This adverse incident is the first ever incident on this product range since launch back in September 2007.

2. Can an end user still drive a motor vehicle without a mechanical thumb release fitted?

YES, as long as the end user follows the re-issued user instructions and opens the Fingers and Thumb with sufficient gap to allow the hand to be removed from the activity its being used for and then turn POWER OFF to the custom Prosthesis / Socket or the hand itself.

If in any doubt, the end user should consult with their registered Clinician / Health Professional.

3. What should an end user do in the event of a major device malfunction?

Patient safety is first priority. If the device can be removed from the activity it's being used for then do so safely and then contact your registered Trust or Clinician / Health professional to arrange for the return and repair to Hugh Steeper Ltd.

If the device cannot be removed from the activity it's being used for, the socket / prosthesis must be removed from the residual limb and then if possible, the hand removed from this and be returned for repair to Hugh Steeper Ltd through your registered Trust or Clinician / Health professional.

4. When will the Customer be able to return the hand for update and how will the update take?

The update will be available from 1st May 2019. Once the hand is received, the target is to update and return to the Customer within 7-10 working days.

Annex 1 – Affected (Adult) hand variant and serial number list.

Product	S/No	Product	S/No	Product	S/No	Product	S/No	Product	S/No
MYA775LQD	MYA000634	MYA825RFW	MYA000684	MYA825RQD	MYA000734	MYA775RQD	MYA000784	MYA725RQD	MYA000834
MYA775RQD	MYA000635	MYA775LFW	MYA000685	MYA775LQD	MYA000735	MYA825RQD	MYA000785	MYA825RQD	MYA000835
MYA775RFW	MYA000636	MYA775LFW	MYA000686	MYA725LQD	MYA000736	MYA825RQD	MYA000786	MYA725RQD	MYA000836
MYA725RFW	MYA000637	MYA825RFW	MYA000687	MYA775LQD	MYA000737	MYA825LNA	MYA000787	MYA775RFW	MYA000837
MYA775RNA	MYA000638	MYA775LFW	MYA000688	MYA725RNA	MYA000738	MYA725LQD	MYA000788	MYA775RFW	MYA000838
MYA775RQD	MYA000639	MYA775LFW	MYA000689	MYA775RQD	MYA000739	MYA825RQD	MYA000789	MYA775RQD	MYA000839
MYA775RQD	MYA000640	MYA775RQD	MYA000690	MYA825RQD	MYA000740	MYA775LQD	MYA000790	MYA775LQD	MYA000840
MYA775RFW	MYA000641	MYA775LQD	MYA000691	MYA775LQD	MYA000741	MYA725LQD	MYA000791	MYA775LQD	MYA000841
MYA775RQD	MYA000642	MYA775RQD	MYA000692	MYA725LQD	MYA000742	MYA825RQD	MYA000792	MYA825LQD	MYA000842
MYA775RQD	MYA000643	MYA775RQD	MYA000693	MYA825LQD	MYA000743	MYA825LQD	MYA000793	MYA775LQD	MYA000843
MYA775LQD	MYA000644	MYA725RFW	MYA000694	MYA775RQD	MYA000744	MYA725LQD	MYA000794	MYA775RQD	MYA000844
MYA775RFW	MYA000645	MYA775RFW	MYA000695	MYA775RQD	MYA000745	MYA775RQD	MYA000795	MYA775RQD	MYA000845
MYA825LFW	MYA000646	MYA725RFW	MYA000696	MYA775REU	MYA000746	MYA775LQD	MYA000796	MYA775RQD	MYA000846
MYA775RQD	MYA000647	MYA725RFW	MYA000697	MTA775RQD	MYA000747	MYA775RQD	MYA000797	MYA725RFW	MYA000847
MYA775RQD	MYA000648	MYA775LQD	MYA000698	MYA775LQD	MYA000748	MYA775LQD	MYA000798	MYA725RFW	MYA000848
MYA825RNA	MYA000649	MYA775LQD	MYA000699	MYA775REU	MYA000749	MYA825RNA	MYA000799	MYA775RNA	MYA000849
MYA775RFW	MYA000650	MYA775LQD	MYA000700	MYA775RQD	MYA000750	MYA775RQD	MYA000800	MYA775RQD	MYA000850
MYA775LQD	MYA000651	MYA825LQD	MYA000701	MYA775RQD	MYA000751	MYA725LQD	MYA000801	MYA725LNA	MYA000851
MYA775LQD	MYA000652	MYA825LFW	MYA000702	MYA825LQD	MYA000752	MYA775LQD	MYA000802	MYA775RQD	MYA000852
MYA825LQD	MYA000653	MYA825LQD	MYA000703	MYA775LQD	MYA000753	MYA775LQD	MYA000803	MYA775RQD	MYA000853
MYA775LQD	MYA000654	MYA825LFW	MYA000704	MYA775LQD	MYA000754	MYA825RQD	MYA000804	MYA775LQD	MYA000854
MYA775RQD	MYA000655	MYA725RFW	MYA000705	MTA775RQD	MYA000755	MYA825LQD	MYA000805	MYA725LFW	MYA000855
MYA775RQD	MYA000656	MYA775RFW	MYA000706	MYA775LQD	MYA000756	MYA725LQD	MYA000806	MYA725LFW	MYA000856
MYA725RQD	MYA000657	MYA775RFW	MYA000707	MYA725LEU	MYA000757	MYA725LEU	MYA000807	MYA825RQD	MYA000857
MYA825RQD	MYA000658	MYA775RFW	MYA000708	MYA825RQD	MYA000758	MYA775LQD	MYA000808	MYA775RFW	MYA000858
MYA775LQD	MYA000659	MYA775RFW	MYA000709	MYA825RFW	MYA000759	MYA775LQD	MYA000809	MYA775RFW	MYA000859
MYA825LQD	MYA000660	MYA825RFW	MYA000710	MYA725LQD	MYA000760	MYA775LQD	MYA000810	MYA725RFW	MYA000860
MYA725LQD	MYA000661	MYA775LQD	MYA000711	MYA775RQD	MYA000761	MYA775LQD	MYA000811	MYA825RFW	MYA000861
MYA725LNA	MYA000662	MYA725RFW	MYA000712	MYA775LQD	MYA000762	MYA775LQD	MYA000812	MYA775LQD	MYA000862
MYA725LQD	MYA000663	MYA725RFW	MYA000713	MYA775LQD	MYA000763	MYA775LQD	MYA000813	MYA775LQD	MYA000863
MYA725LQD	MYA000664	MYA725LFW	MYA000714	MYA775LQD	MYA000764	MYA775LQD	MYA000814	MYA775LQD	MYA000864
MYA825RNA	MYA000665	MYA825RQD	MYA000715	MYA725LQD	MYA000765	MYA775LQD	MYA000815	MYA775RQD	MYA000865
	MYA000666	MYA825LNA	MYA000716	MYA725LQD	MYA000766	MYA775RQD	MYA000816	MYA775RQD	MYA000866
MYA825LNA	MYA000667	MHA825RQD	MYA000717	MYA725RNA	MYA000767	MYA775RQD	MYA000817	MYA775REU	MYA000867
MYA725LFW	MYA000668	MYA775RFW	MYA000718	MYA725RQD	MYA000768	MYA775RQD	MYA000818	MYA825LQD	MYA000868
MYA725RQD	MYA000669	MYA775LFW	MYA000719	MYA725RQD	MYA000769	MYA775RQD	MYA000819	MYA775LFW	MYA000869
MYA775RQD	MYA000670	MYA825LFW	MYA000720	MYA725LNA	MYA000770	MYA775RQD	MYA000820	MYA825RQD	MYA000870
MYA775LQD	MYA000671	MYA825LFW	MYA000721	MYA775RQD	MYA000771	MYA775RQD	MYA000821	MYA775LFW	MYA000871
MYA775LQD	MYA000672	MYA775RQD	MYA000722	MYA775RQD	MYA000772	MYA775RQD	MYA000822	MYA825LQD	MYA000872
MYA775LQD	MYA000673	MYA775RQD	MYA000723	MYA775RQD	MYA000773	MYA775RQD	MYA000823	MYA775RQD	MYA000873
MYA825LFW	MYA000674	MYA775LFW	MYA000724	MYA825RFW	MYA000774	MYA775RQD	MYA000824	MYA775LQD	MYA000874
MYA775RQD	MYA000675	MYA775RQD	MYA000725	MYA725LFW	MYA000775	MYA775RFW	MYA000825	MYA725LQD	MYA000875
MYA775RQD	MYA000676	MYA775LQD	MYA000726	MYA775LFW	MYA000776	MYA775LFW	MYA000826	MYA725RQD	MYA000876
MYA725LFW	MYA000677	MYA775LQD	MYA000727	MYA725RFW	MYA000777	MYA725LFW	MYA000827	MYA775RQD	MYA000877
MYA825RFW	MYA000678	MYA775RQD	MYA000728	MYA725RQD	MYA000778	MYA775RQD	MYA000828	MYA725RQD	MYA000878
MYA725LFW	MYA000679	MYA775LQD	MYA000729	MYA775RQD	MYA000779	MYA725RFW	MYA000829	MYA725RQD	MYA000879
MYA725LFW	MYA000680	MYA775LQD	MYA000730	MYA775RQD	MYA000780	MYA725RQD	MYA000830	MYA825RQD	MYA000880
MYA725LFW	MYA000681	MYA725RFW	MYA000731	MYA775RQD	MYA000781	MYA775LQD	MYA000831	MYA825RQD	MYA000881
MYA725LFW	MYA000682	MYA775RQD	MYA000732	MYA775LQD	MYA000782	MYA725LQD	MYA000832	MYA825RQD	MYA000882
MYA825RFW	MYA000683	MYA775LQD	MYA000733	MYA825LQD	MYA000783	MYA725RNA	MYA000833	MYA825LQD	MYA000883
MYA775RQD	MYA000934	MYA725LFW	MYA000985	MYA725LQD	MYA001036	MYA775RQD	MYA001087	MYA725LFW	MYA001137
MYA775RQD	MYA000935	MYA775LFW	MYA000986	MYA775LQD	MYA001037	MYA775RQD	MYA001088	MYA725LFW	MYA001138
MYA775RQD	MYA000936	MYA775LFW	MYA000987	MYA775RQD	MYA001038	MYA775RQD	MYA001089	MYA725LFW	MYA001139
MYA725LFW	MYA000937	MYA725RFW	MYA000988	MYA775LQD	MYA001039	MYA775RQD	MYA001090	MYA825RFW	MYA001140
MYA725LFW	MYA000938	MYA725RFW	MYA000989	MYA775LQD	MYA001040	MYA775RQD	MYA001091	MYA825RFW	MYA001141
MYA725LFW	MYA000939	MYA825RQD	MYA000990	MYA825RQD	MYA001041	MYA775RQD	MYA001092	MYA825RFW	MYA001142
MYA725LFW	MYA000940	MYA775LQD	MYA000991	MYA775LQD	MYA001042	MYA775RQD	MYA001093	MYA825LFW	MYA001143
MYA725RFW	MYA000941	MYA775RFW	MYA000992	MYA775LFW	MYA001044	MYA775RQD	MYA001094	MYA825LFW	MYA001144
MYA725RFW	MYA000942	MYA775RFW	MYA000993	MYA775RQD	MYA001045	MYA775LQD	MYA001095	MYA825LQD	MYA001145
MYA725RFW	MYA000943	MYA775RFW	MYA000994	MYA775RQD	MYA001046	MYA775RQD	MYA001096	MYA775LQD	MYA001146
MYA725RFW	MYA000944	MYA775LFW	MYA000995	MYA775LQD	MYA001047	MYA825RFW	MYA001097	MYA725RQD	MYA001147
MYA775LFW	MYA000945	MYA775LFW	MYA000996	MYA775LQD	MYA001048	MYA725LFW	MYA001098	MYA775RQD	MYA001148
MYA775LFW	MYA000946	MYA775LQD	MYA000997	MYA775RQD	MYA001049	MYA775RFW	MYA001099	MYA825RQD	MYA001149
MYA775LFW	MYA000947	MYA775RQD	MYA000998	MYA775RQD	MYA001050	MYA825LFW	MYA001100	MYA775REU	MYA001150
MYA775LFW	MYA000948	MYA775LQD	MYA000999	MYA775LFW	MYA001051	MYA725LFW	MYA001101	MYA775REU	MYA001151
MYA725LFW	MYA000949	MYA775RQD	MYA001000	MYA775LQD	MYA001052	MYA775RQD	MYA001102	MYA775REU	MYA001152
MYA725LFW	MYA000950	MYA825RFW	MYA001001	MYA775LQD	MYA001053	MYA775RQD	MYA001103	MYA775RQD	MYA001153
MYA725RFW	MYA000951	MYA825LQD	MYA001002	MYA725RFW	MYA001054	MYA775RQD	MYA001104	MYA775RQD	MYA001154
MYA725RFW	MYA000952	MYA775LQD	MYA001003	MYA725RQD	MYA001055	MYA775RQD	MYA001105	MYA775RQD	MYA001155
MYA775RFW	MYA000953	MYA825RQD	MYA001004	MYA775RQD	MYA001056	MYA725LNA	MYA001106	MYA775RFW	MYA001156
MYA725RNA	MYA000954	MYA725RQD	MYA001005	MYA725RQD	MYA001057	MYA825RQD	MYA001107	MYA825RQD	MYA001157
MYA825RQD	MYA000955	MYA775RFW	MYA001006	MYA775RQD	MYA001058	MYA775RQD	MYA001108	MYA825RFW	MYA001158
MYA775LQD	MYA000956	MYA775RQD	MYA001007	MYA725RQD	MYA001059	MYA725RFW	MYA001109	MYA775RFW	MYA001159
MYA725RQD	MYA000958	MYA775LQD	MYA001008	MYA775LFW	MYA001060	MYA775RQD	MYA001110	MYA725LNA	MYA001160
MYA825RQD	MYA000959	MYA825RQD	MYA001009	MYA725LQD	MYA001061	MYA825LQD	MYA001111	MYA775RQD	MYA001161
MYA775RQD	MYA000960	MYA775RQD	MYA001010	MYA725LQD	MYA001062	MYA775RFW	MYA001112	MYA775LQD	MYA001162
MYA725LQD	MYA000961	MYA775LQD	MYA001011	MYA775RQD	MYA001063	MYA775RQD	MYA001113	MYA775LFW	MYA001163
MYA775LQD	MYA000962	MYA775LQD	MYA001012	MYA725LFW	MYA001064	MYA775LQD	MYA001114	MYA725RFW	MYA001164
MYA775LFW	MYA000963	MYA775LQD	MYA001013	MYA825LQD	MYA001065	MYA775RQD	MYA001115	MYA725RFW	MYA001165
MYA725LQD	MYA000964	MYA775LFW	MYA001014	MYA825RQD	MYA001066	MYA775LQD	MYA001116	MYA825LFW	MYA001166

MYA725LQD	MYA000965	MYA725RQD	MYA001015	MYA775LQD	MYA001067	MYA725RQD	MYA001117	MYA725RQD	MYA001167
MYA825LQD	MYA000966	MYA775RQD	MYA001016	MYA775RQD	MYA001068	MYA825RQD	MYA001118		
MYA725LQD	MYA000967	MYA825LQD	MYA001017	MYA825LQD	MYA001069	MYA825RQD	MYA001119		
MYA775RQD	MYA000968	MYA775LQD	MYA001018	MYA725RQD	MYA001070	MYA825RQD	MYA001120		
MYA825LQD	MYA000969	MYA725RQD	MYA001019	MYA725RQD	MYA001071	MYA775RQD	MYA001121		
MYA775RQD	MYA000970	MYA825RQD	MYA001020	MYA725RQD	MYA001072	MYA825RQD	MYA001122		
MYA825RQD	MYA000971	MYA825RQD	MYA001021	MYA775RQD	MYA001073	MYA825RQD	MYA001123		
MYA825RQD	MYA000972	MYA775LQD	MYA001022	MYA775RQD	MYA001074	MYA775RQD	MYA001124		
MYA775LQD	MYA000973	MYA775LQD	MYA001023	MYA775LQD	MYA001075	MYA725RQD	MYA001125		
MYA775LQD	MYA000974	MYA825RQD	MYA001025	MYA775LQD	MYA001076	MYA825RQD	MYA001126		
MYA825LQD	MYA000975	MYA725RQD	MYA001026	MYA725RQD	MYA001077	MYA775LQD	MYA001127		
MYA825RQD	MYA000976	MYA775LQD	MYA001027	MYA775RQD	MYA001078	MYA775RQD	MYA001128		
MYA825LQD	MYA000977	MYA775RQD	MYA001028	MYA775RQD	MYA001079	MYA775RQD	MYA001129		
MYA825LQD	MYA000978	MYA825RQD	MYA001029	MYA775LQD	MYA001080	MYA775RQD	MYA001130		
MYA775RQD	MYA000979	MYA825LQD	MYA001030	MYA775LQD	MYA001081	MYA725RQD	MYA001131		
MYA775RQD	MYA000980	MYA825LQD	MYA001031	MYA775LQD	MYA001082	MYA725RQD	MYA001132		
MYA725LQD	MYA000981	MYA725RQD	MYA001032	MYA775LQD	MYA001083	MYA725RQD	MYA001133		
MYA725LQD	MYA000982	MYA775RQD	MYA001033	MYA775LQD	MYA001084	MYA775LQD	MYA001134		
MYA725LQD	MYA000983	MYA775LQD	MYA001034	MYA775LQD	MYA001085	MYA775LQD	MYA001135		
MYA725LQD	MYA000984	MYA725LQD	MYA001035	MYA775RQD	MYA001086	MYA775LQD	MYA001136		

Affected (Junior) hand variant and serial number list.

Product	S/No	Product	S/No
MYA675RQD	MYJ00022	MYA675RQD	MYJ00106
MYA675LQD	MYJ00048	MYA675LQD	MYJ00107
MYA675RQD	MYJ00059	MYA675LQD	MYJ00108
MYA675RQD	MYJ00060	MYA675LQD	MYJ00109
MYA675LQD	MYJ00061	MYA675LQD	MYJ00110
MYA675LQD	MYJ00062	MYA675RQD	MYJ00111
MYA675RQD	MYJ00063	MYA675RQD	MYJ00112
MYA675LQD	MYJ00064	MYA675LQD	MYJ00113
MYA675RQD	MYJ00065	MYA675LQD	MYJ00114
MYA675RQD	MYJ00066	MYA675LQD	MYJ00115
MYA675LQD	MYJ00067	MYA675LQD	MYJ00116
MYA675LQD	MYJ00068	MYA675LQD	MYJ00117
MYA675RQD	MYJ00069	MYA675RQD	MYJ00118
MYA675RQD	MYJ00070	MYA675RQD	MYJ00119
MYA675RQD	MYJ00071	MYA675RQD	MYJ00120
MTA675RQD	MYJ00072	MYA675RQD	MYJ00121
MYA675RQD	MYJ00073	MYA675RQD	MYJ00122
MYA675RQD	MYJ00074	MYA675RQD	MYJ00123
MYA675RQD	MYJ00075	MYA675LQD	MYJ00124
MYA675RQD	MYJ00076	MYA675LQD	MYJ00125
MYA675RQD	MYJ00077	MYA675LQD	MYJ00126
MYA675LQD	MYJ00078	MYA675RQD	MYJ00127
MYA675LQD	MYJ00079	MYA675LQD	MYJ00128
MYA675LQD	MYJ00080	MYA675LQD	MYJ00129
MYA675RQD	MYJ00081	MYA675LQD	MYJ00130
MYA675LQD	MYJ00082	MYA675LQD	MYJ00131
MYA675RQD	MYJ00083	MYA675LQD	MYJ00132
MYA675RQD	MYJ00084	MYA675RQD	MYJ00133
MYA675LQD	MYJ00085	MYA675LQD	MYJ00134
MYA675RQD	MYJ00086	MYA675LQD	MYJ00135
MYA675LQD	MYJ00087	MYA675LQD	MYJ00136
MYA675LQD	MYJ00088	MYA675RQD	MYJ00137
MYA675LQD	MYJ00089	MYA675RQD	MYJ00138
MYA675LQD	MYJ00090	MYA675LQD	MYJ00139
MYA675LQD	MYJ00091	MYA675LQD	MYJ00140
MYA675LQD	MYJ00092	MYA675LQD	MYJ00141
MYA675RQD	MYJ00093		
MYA675RQD	MYJ00094		
MYA675LQD	MYJ00095		
MYA675RQD	MYJ00096		
MYA675RQD	MYJ00097		
MYA675LQD	MYJ00098		
MYA675LQD	MYJ00099		
MYA675LQD	MYJ00100		
MYA675RQD	MYJ00101		
MYA675RQD	MYJ00102		
MYA675LQD	MYJ00103		
MYA675LQD	MYJ00104		
MYA675LQD	MYJ00105		

Select Myoelectric Hand RETURNS FORM

RTA N° 9999

In order to for us to process your product return, please ensure that this form is completed with the relevant information as stated below.

Note – Please print this completed form and send with the returned hand(s) for processing.

Customer _____ Original Sales Order Number _____

Product Code _____ Product Name _____

Serial N°(s) (as applicable) _____ QTY _____

Postal address for hand return: _____

Disclaimer Statement:

It is the responsibility of the End user / Clinician / Distributor to complete the below section if the end user is no longer using the Prosthesis or does not want to return the product for a free of charge update to the thumb. Please add Customer order details and serial number of the hand below.

The hand serial number can be found on the outside of the box the hand was delivered in, the supplied service card or by removing the inner hand shell and looking at the serial number ident of the chassis frame.

Customer _____ Original Sales Order Number _____

Serial N°(s) (as applicable) _____ QTY _____

Signed _____ Date _____