


# EU Declaration of Conformity

This declaration of conformity is issued under the sole responsibility of **Enraf-Nonius B.V.** Quality Management System according to EN ISO 13485:2016

Model number:	1550000
Product name(s):	ManuXelect Ultra aXionXelect
	Delivery according to configurator 103-1550000-4E
Basic UDI-DI:	871999250815500002V
Intended purpose:	Treatment couch to support a patient during treatment by a physiotherapist
Risk class:	I, according to rule 13 in Annex VIII of (EU) 2017/745
Device marking:	

The device covered by this declaration, in combination with its test certificate is in conformity with:

(EU) 2017/745 (Medical Device Regulation)

2006/42/EC (Machinery Directive)

2011/65/EU as amended by (EU) 2015/863 (RoHS Directive)

Any modifications to the product not authorized by Enraf-Nonius will invalidate this declaration.

**Signed for and on behalf of Enraf-Nonius B.V.:**



T. Doodkorte  
Commercial Director  
Person Responsible for Regulatory Compliance

Place: Rotterdam

Date of issue: 10 November 2023

**Enraf-Nonius B.V.**  
Vareseweg 127  
3047 AT Rotterdam  
The Netherlands  
SRN (NL-MF-000000429)



# ManuXelect series treatment couches

## Configuration code ManuXelect Series

<b>T</b>	<b>F</b>	<b>XX</b>	<b>.</b>	<b>P</b>	<b>SS</b>	<b>.</b>	<b>G</b>	<b>B</b>	<b>W</b>	<b>.</b>	<b>MM</b>	<b>.</b>	<b>V</b>	<b>A</b>	<b>B</b>
type	frame colour	section type	padding	upholstery colour	section width	operation	wheels	motor	packaging	option	option				

### T: frame type

S	ManuXelect electric frame
L	Ultra electric frame
Z	aXionXelect electric frame *
M	ManuXelect electric frame (Linak)
A	aXionXelect electric frame (Linak)
H	ManuXelect hydraulic frame
I	aXionXelect hydraulic frame

### F: frame colour

G	grey (RAL 7035)
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### XX: section type (see next 4 pages)

00	3 sections
01	2 sections, incl. head-section
02	2 sections, incl. back-section
03	Traction (ManuXelect)
04	Traction (aXionXelect)

### P: padding

0	normal
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### S: upholstery colour

00	grey 013
01	sirius blue 004
02	lavender 199 *
03	grey 812 *
04	cornflower blue 169 *
05	red 852 *
06	grey 013 – 80 cm **/**
07	sirius blue 004 – 80 cm **/**
08	lavender 199 – 80 cm **/**
09	sirius blue 204
10	grey 213
12	black 012 *
14	baby blue 170 *
20	grey 213 67 cm 2 sect. no nose*
21	grey 213 80 cm 2 sect. no nose*

### G: section width

0	67 cm
1	80 cm *

### B: operation

H	hand switch
I	hand switch (for frame type M,A)
V	foot switch
G	foot switch (for frame type M,A)
R	all-around
O	all-around aXionXelect
A	all-around (for frame type M,A)
P	hydraulic (for frame type H,I)

### W: wheels

0	no wheels
K	small wheels

### MM: motor

00	150 kg - 230 Volt euro
01	150 kg - 230 Volt UK
02	150 kg - 115 Volt USA
03	150 kg + lock box ***
04	250 kg + lock box ***
10	250 kg - 230 Volt euro
11	250 kg - 230 Volt UK
12	250 kg - 115 Volt USA
13	250 kg - 115 Volt (hospital grade)
14	150 kg - 230 Volt CH
15	250 kg - 230 Volt CH
20	150 kg + autolock box
30	250 kg + autolock box
88	Ultra motor
60	Linak - euro (for frame type M,A)
61	Linak - UK (for frame type M,A)
62	Linak - JP (for frame type M,A)
63	Linak - USA (for frame type M,A)
64	Linak - CH (for frame type M,A)
65	Linak incl autolock - euro (for frame type M,A)
66	Linak incl autolock - UK (for frame type M,A)

67	Linak incl autolock - JP (for frame type M,A)
68	Linak incl autolock - USA (for frame type M,A)
69	Linak incl autolock - CH (for frame type M,A)
90	hydraulic pump (for frame type H,I)

### V: packaging

S	standard packaging
E	export packaging 67 cm
Z	aXionXelect packaging
B	export packaging 80 cm
O	no packaging

### A: options \*

0	no
1	Paper roll holder
A	Fixation Horn
B	Gyno support Set Basic
C	Gyno Support Set Comfort
D	1 + A
E	1 + B
F	1 + C
G	D + B
H	D + C
I	A + B
J	A + C

### B: options

0	no
1	nose plug
2	Clamp Gyno/Shoulder/Armpit *
3	Clamp Gyno/Armpit *
4	Clamp Shoulder *
5	1 + 2 *
6	1 + 3 *
7	1 + 4 *
8	Fold down support *

\* Not for section type 03 and type 04 (traction).

\*\* Only for section type 01 (2 sections including head-section) and until stocks run out.

\*\*\* Not for type Z (aXionXelect electric frame).



## ManuXelect series treatment couches

# TF00.PSS.GBW.MM.VAB

### 3 sections

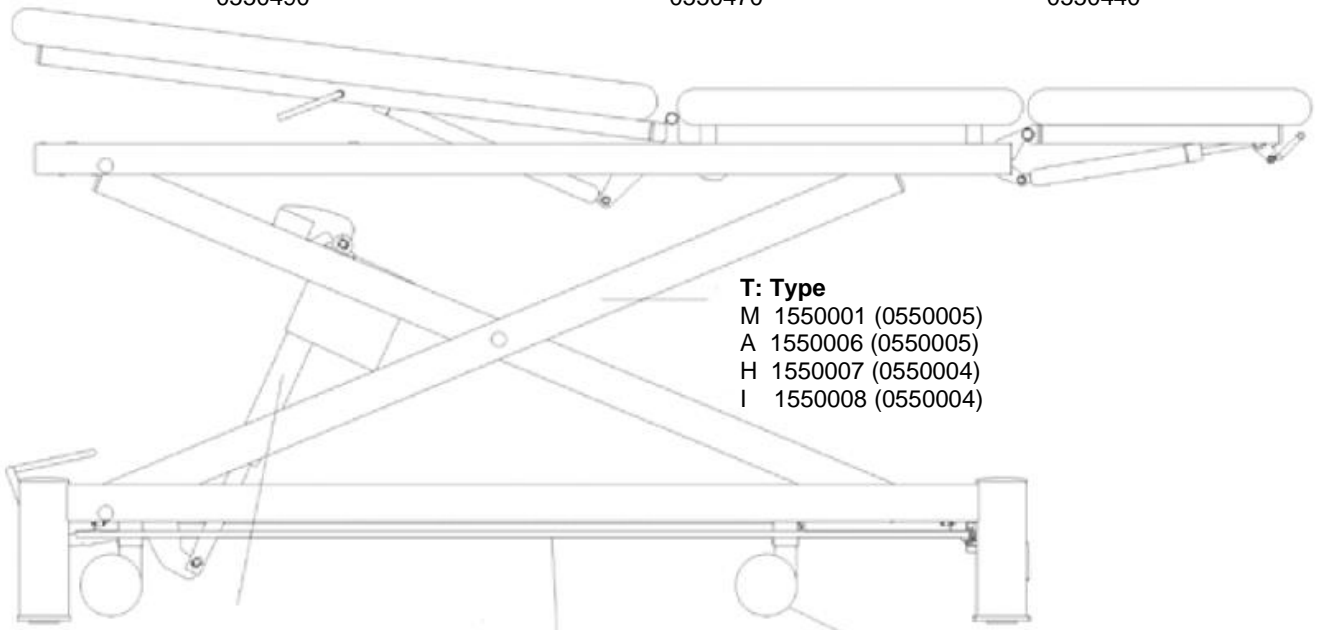
#### S: Upholstery Colour

02 8021001 / 8023001 / 8026101  
04 8021002 / 8023002 / 8026102  
09 8021004 / 8023004 / 8026104  
10 8021003 / 8023003 / 8026103  
12 8021005 / 8023005 / 8026105  
14 8021006 / 8023006 / 8026106

Assembly Material  
Back Section  
0550490

Assembly Material  
Middle Section  
0550470

Assembly Material  
Head Section  
0550440



#### T: Type

M 1550001 (0550005)  
A 1550006 (0550005)  
H 1550007 (0550004)  
I 1550008 (0550004)

#### MM: Motor

60 3496213 / 3496226 / 3496676  
61 3496213 / 3496226 / 3496678  
62 3496213 / 3496226 / 3496680  
63 3496213 / 3496226 / 3496681  
64 3496213 / 3496226 / 3496679  
65 3496213 / 3496226 / 3496676 / 1550017  
66 3496213 / 3496226 / 3496678 / 1550017  
67 3496213 / 3496226 / 3496680 / 1550017  
68 3496213 / 3496226 / 3496681 / 1550017  
69 3496213 / 3496226 / 3496679 / 1550017  
90 3496231

#### B: Operation

I 3496221  
G 3496222  
A 0550331  
P -

#### W: Wheels

O -  
K 1550025



## ManuXelect series treatment couches

# TF01.PSS.GBW.MM.VAB

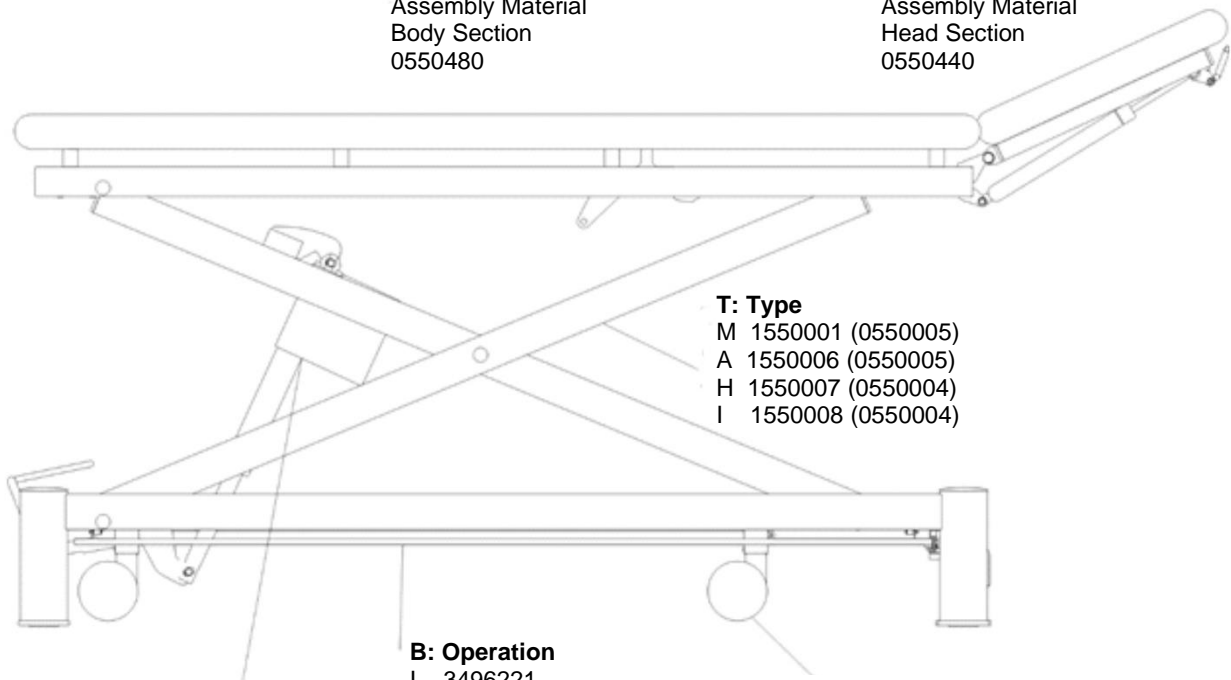
### 2 Sections including head-section

#### S: Upholstery Colour

- 02 8021001 / 8025001
- 04 8021002 / 8025002
- 08 1550242 \*\*
- 09 8021004 / 8025004
- 10 8021003 / 8025003
- 12 8021005 / 8025005
- 14 8021006 / 8025006

Assembly Material  
Body Section  
0550480

Assembly Material  
Head Section  
0550440



#### T: Type

- M 1550001 (0550005)
- A 1550006 (0550005)
- H 1550007 (0550004)
- I 1550008 (0550004)

#### B: Operation

- I 3496221
- G 3496222
- A 0550331
- P -

#### W: Wheels

- O -
- K 1550025

#### MM: Motor

- 60 3496213 / 3496226 / 3496676
- 61 3496213 / 3496226 / 3496678
- 62 3496213 / 3496226 / 3496680
- 63 3496213 / 3496226 / 3496681
- 64 3496213 / 3496226 / 3496679
- 65 3496213 / 3496226 / 3496676 / 1550017
- 66 3496213 / 3496226 / 3496678 / 1550017
- 67 3496213 / 3496226 / 3496680 / 1550017
- 68 3496213 / 3496226 / 3496681 / 1550017
- 69 3496213 / 3496226 / 3496679 / 1550017
- 90 3496231



## ManuXelect series treatment couches

# TF02.PSS.GBW.MM.VAB

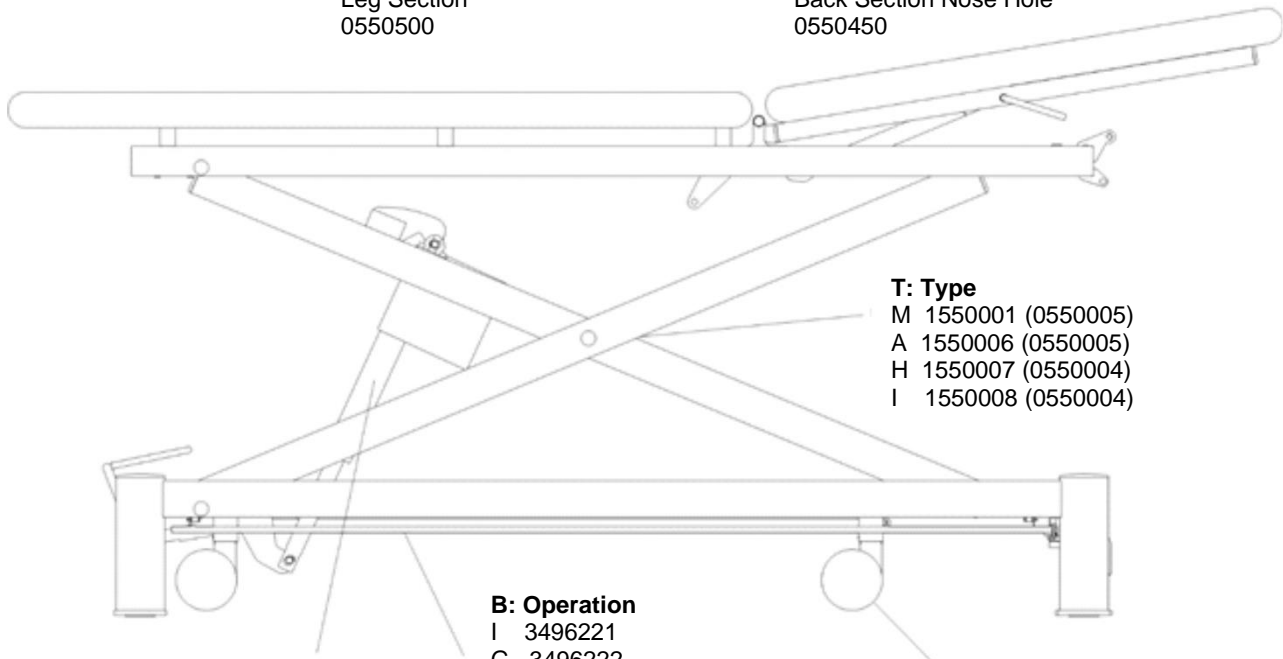
### 2 Sections including back-section

#### S: Upholstery Colour

- 02 8026001 / 8024001
- 04 8026002 / 8024002
- 09 8026004 / 8024004
- 10 8026003 / 8024003
- 12 8026005 / 8024005
- 14 8026006 / 8024006
- 20 1550286
- 21 1550296

Assembly Material  
Leg Section  
0550500

Assembly Material  
Back Section Nose Hole  
0550450



#### T: Type

- M 1550001 (0550005)
- A 1550006 (0550005)
- H 1550007 (0550004)
- I 1550008 (0550004)

#### B: Operation

- I 3496221
- G 3496222
- A 0550331
- P -

#### W: Wheels

- O -
- K 1550025

#### MM: Motor

- 60 3496213 / 3496226 / 3496676
- 61 3496213 / 3496226 / 3496678
- 62 3496213 / 3496226 / 3496680
- 63 3496213 / 3496226 / 3496681
- 64 3496213 / 3496226 / 3496679
- 65 3496213 / 3496226 / 3496676 / 1550017
- 66 3496213 / 3496226 / 3496678 / 1550017
- 67 3496213 / 3496226 / 3496680 / 1550017
- 68 3496213 / 3496226 / 3496681 / 1550017
- 69 3496213 / 3496226 / 3496679 / 1550017
- 90 3496231



# ManuXelect series treatment couches

## TF03.PSS.GBW.MM.VAB

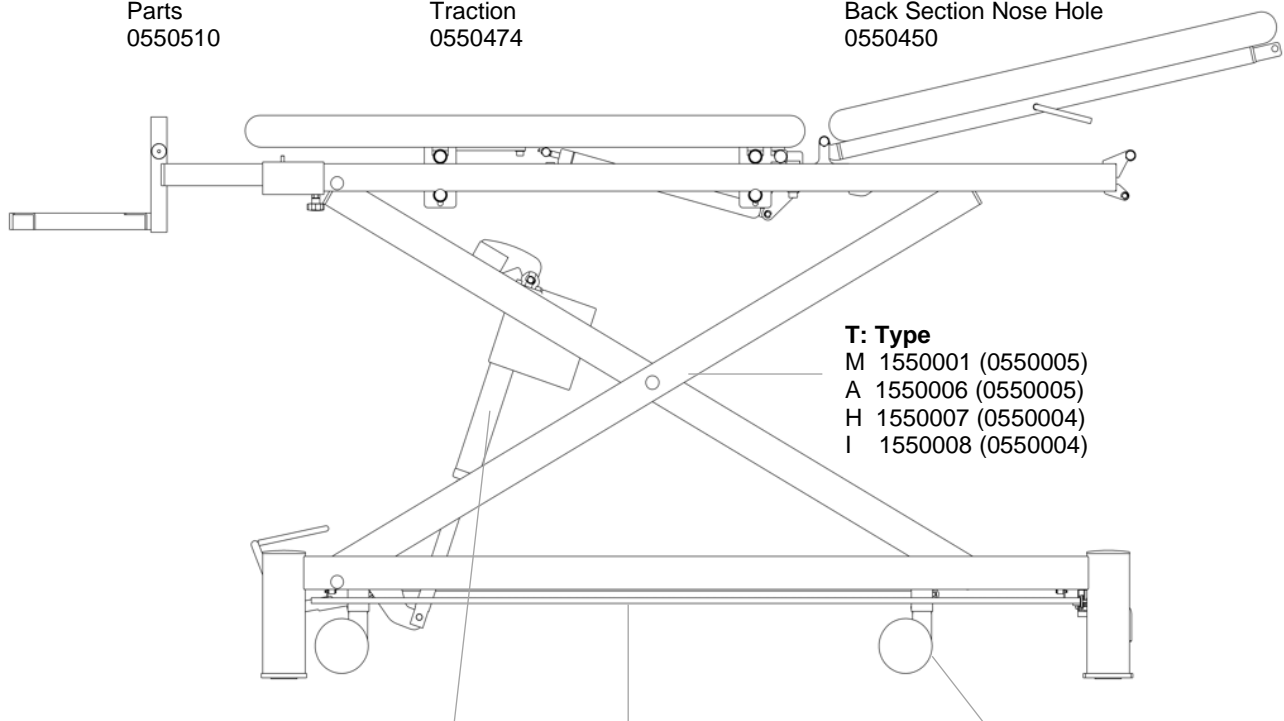
### 2-Section Traction

**S: Upholstery Colour**  
 09 8026004 / 8026104  
 10 8026003 / 8026103

**Group Traction  
 Parts**  
 0550510

**Assembly Material  
 Traction**  
 0550474

**Assembly Material  
 Back Section Nose Hole**  
 0550450



**T: Type**  
 M 1550001 (0550005)  
 A 1550006 (0550005)  
 H 1550007 (0550004)  
 I 1550008 (0550004)

**MM: Motor**

- 60 3496213 / 3496226 / 3496676
- 61 3496213 / 3496226 / 3496678
- 62 3496213 / 3496226 / 3496680
- 63 3496213 / 3496226 / 3496681
- 64 3496213 / 3496226 / 3496679
- 65 3496213 / 3496226 / 3496676 / 1550017
- 66 3496213 / 3496226 / 3496678 / 1550017
- 67 3496213 / 3496226 / 3496680 / 1550017
- 68 3496213 / 3496226 / 3496681 / 1550017
- 69 3496213 / 3496226 / 3496679 / 1550017
- 90 3496231

**B: Operation**

- I 3496221
- G 3496222
- A 0550331
- P -

**W: Wheels**

- O -
- K 1550025



# ManuXelect series treatment couches

## TF04.PSS.GBW.MM.VAB

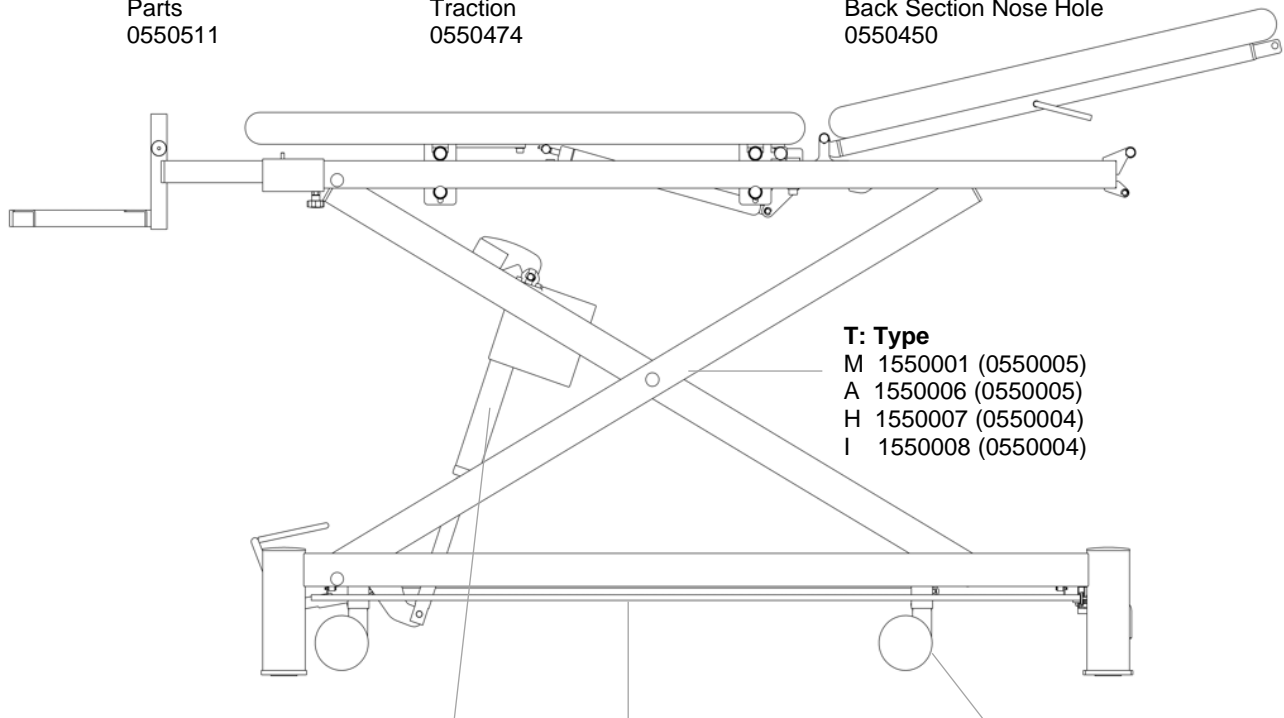
### 2-Section Traction

**S: Upholstery Colour**  
 09 8026004 / 8026104  
 10 8026003 / 8026103

**Group Traction  
 Parts**  
 0550511

**Assembly Material  
 Traction**  
 0550474

**Assembly Material  
 Back Section Nose Hole**  
 0550450



**T: Type**  
 M 1550001 (0550005)  
 A 1550006 (0550005)  
 H 1550007 (0550004)  
 I 1550008 (0550004)

**MM: Motor**

- 60 3496213 / 3496226 / 3496676
- 61 3496213 / 3496226 / 3496678
- 62 3496213 / 3496226 / 3496680
- 63 3496213 / 3496226 / 3496681
- 64 3496213 / 3496226 / 3496679
- 65 3496213 / 3496226 / 3496676 / 1550017
- 66 3496213 / 3496226 / 3496678 / 1550017
- 67 3496213 / 3496226 / 3496680 / 1550017
- 68 3496213 / 3496226 / 3496681 / 1550017
- 69 3496213 / 3496226 / 3496679 / 1550017
- 90 3496231

**B: Operation**

- I 3496221
- G 3496222
- A 0550331
- P -

**W: Wheels**

- O -
- K 1550025