

IFU (Instructions for Use)

♣ Company name : SOYEE PRODUCT INC.

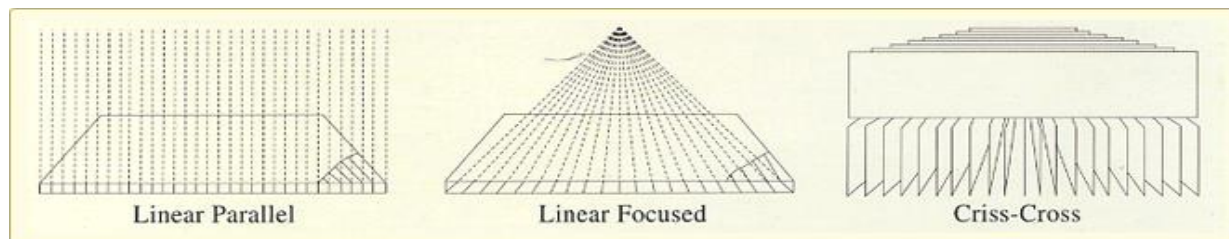
♣ Item name : X-ray Grid

1. SPECIFICATIONS OF SOYEE X-RAY GRIDS

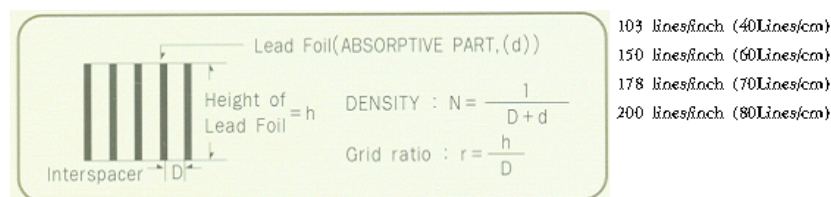
Grid Composition Part	Density		Interspacer		X-Ray absorbing part	
	100 L/Inch(40L/cm)		0.20mm Aluminum		0.04mm Lead	
	150 L/Inch(60L/cm)		0.12mm Aluminum		0.04mm Lead	
	178 L/Inch(70L/cm)		0.10mm Aluminum		0.04mm Lead	
	200 L/Inch(80L/cm)		0.10mm Aluminum		0.025mm Lead	
	215 L/Inch(85L/cm)		0.09mm Aluminum		0.025mm Lead	
	230 L/Inch(90L/cm)		0.08mm Aluminum		0.025mm Lead	
Thickness of Ratio Line/Inch(Line/cm)		6:1	8:1	10:1	12:1	15:1
100 L/Inch(40L/cm)		1.6mm(1.2)	2.0mm(1.6)	2.4mm(2.0)	2.8mm(2.4)	3.2mm(2.8)
152 L/Inch(60L/cm)		1.02mm(0.72)	1.26mm(0.96)	1.5mm(1.2)	1.74mm(1.44)	2.1mm(1.8)
178 L/Inch(70L/cm)			1.04mm(0.96)	1.24mm(1.0)	1.44mm(1.20)	1.74mm(1.50)
200 L/Inch(80L/cm)			0.94mm(0.64)	1.04mm(0.8)	1.20mm(0.96)	1.44mm(1.20)

MARKING : SIZE, TUBE SIDE, CENTER LINE, RATIO, DENSITY, FOCAL DISTANCE, SERIAL NO

2. THREE TYPES OF LEAD STRIP POSITIONING



3. RATIO : Available from 6:1 to 15:1 DENSITY : AVAILABLE IN FIVE TYPES



4. FOCAL RANGE

Focal Range		Ratio	Type
Inch	Metric(cm)		
28-48, 48-72	71-122, 122-183	5:1	Focused
48 to infinity	122-infinity	5:1	Parallel
28-48, 48-72	71-122, 122-183	6:1	Focused
48 to infinity	122-infinity	6:1	Parallel
26-32, 34-44, 48-72	66-81, 86-122, 122-183	8:1	Focused
36-40, 60-72	91-102, 152-183	10:1	Focused
36-40, 60-72	91-102, 152-183	12:1	Focused

- Standard focal ranges available:
 Short(26" –32"), Medium(34" –44),
 Long(40" –72", 48" –72", or 60" –72)
 and infinity (parallel). Special focal
 ranges may be accommodated per your
 specifications.

5. PARALLEL GRID

Parallel grids are used for operational research and traumatology since exact centering is impossible in this case. The scattered radiation absorbing strips are vertical and parallel to the grid surface. The strips, generally, run parallel to the long dimension of the grid. In order to get a vivid radiograph, focal distance of parallel grids must be 150cm–infinity since the scattered radiation absorbing strips are not exactly parallel to the diverging radiation.

6. FOCUSED GRID

Type	Grid Density	Ratio	Focal Distance (fo)	Focal Range (f1 to f2) of standard focal distance (fo) By IEC standards for a grid		
				short (fo=80cm)	medium (fo=100cm)	ling (fo=150cm)
Focused	40 lines/cm (100 lines/inch)	6:1	any distances available over 65cm	65 to 100	75 to 150	100 to 200
		8:1		70 to 100	80 to 130	110 to 200
		10:1		70 to 90	80 to 120	120 to 200
		12:1		70 to 90	90 to 120	120 to 200
		15:1		79 to 81	99 to 101	147 to 153
	60 lines/cm (152 lines/inch)	6:1	any distances	65 to 100	75 to 150	100 to 200
		8:1	available	70 to 100	80 to 130	110 to 200
		10:1	over 65cm	70 to 90	90 to 120	120 to 200

		12:1 15:1		70 to 90 79 to 81	90 to 120 99 to 101	120 to 200 147 to 153
	70 lines/cm (178 lines/inch)	8:1 10:1 12:1 15:1	any distances available over 70cm	70 to 100 70 to 90 70 to 90 75 to 90	80 to 130 90 to 120 90 to 120 90 to 110	110 to 200 120 to 190 120 to 200 130 to 200
	80 lines/cm (200 lines/inch)	8:1 10:1 12:1 15:1	any distances available over 70-cm	70 to 100 70 to 90 70 to 90 75 to 90	80 to 130 90 to 120 90 to 120 90 to 110	110 to 200 120 to 190 120 to 200 130 to 200
	Parallel	40 lines/cm (100 lines/inch)	6:1	165 to infinity		
	Crossed (Focused or Parallel)	40 lines/cm (100 lines/inch)	6:1	refer to the above 6:1 ratio grid in focused or parallel section.		

7. STANDARD SIZE OF SOYEE X-RAY GRIDS

GRID		CIRCULAR GRID	REMAKRS
13 X 18cm	5 x 7"	Circular 10" Circular 9" Circular 22.8cm Circular 19.4cm	All sizes you want are available including circular grid.
18 x 24cm	8 x 10"		
24 x 30cm	10 x 12"		
30 x 40cm	11 x 14"		
35 x 35cm	14 x 14"		
35 x 43cm	14 x 17"		
46 x 46cm or 457 x 457mm	17-1/4 x 17-3/4"		
48 x 44cm or 480 x 438mm	17-1/4 x 18-7/8" or 18 x 18"		
35 x 91cm	14 x 36"		
38 x 94cm	15 x 37"		
35 x 129cm	14 x 51"		

8. SELECTION OF HIGH PRECISION MATERIALS

To obtain the most effective X-Ray transmission and absorption, as well as grid density uniformity and precise geometric arrangement for strip focussing, sojee employs the finest precision materials, such as aluminum strips with a purity of more than 99.50% and a thickness of $+0, -0.02\text{mm}$, and lead strips with a purity of more than 95.70% and a thickness tolerance of $+0, -0.004\text{mm}$.

9. DURABILITY & INSPECTION

Each Grid strip is laminated and baked after the gluing procedure. This ensures absolute rigidity between the strips, as well as heat and moisture resistance, and completely prevents warping and cracking over the course of time. Each grids is subjected to radiographic testing prior to shipment, and only those Grids which have passed the test for perfect strip alignment are delivered to our customers.

The test film supplied with all our Grids is your assurance of quality.

10. COMPONENTS

Lead foil : to be used in order to absorb the scattered radiation.

Interspacer : Material between the Lead foils, which absorbs the X-ray less.

Aluminum is used as an interspacer which makes easy to supply & demand and to manufacture the products.

Aluminum (Al), Paper (Pa), Wood (Wo), Polyester (P1),

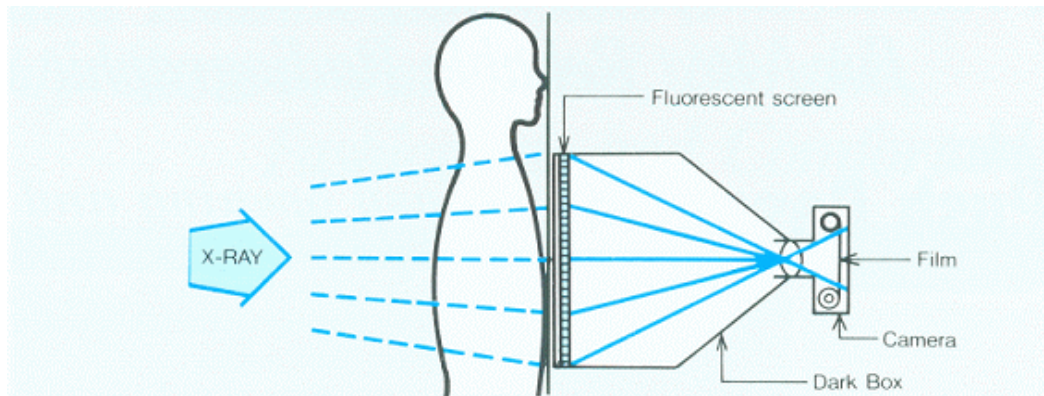
Carbon Fiber-Reinforced Plastics (Cfrp), etc. are in use.

Mark on the Grid

- a) Item Name
- b) Manufacturer
- c) Manufacturer's license Nr. (In case if domestic market)
- d) dimension, density, ratio, center line, focal distance, interspaced material , observing X-ray

11. HOW TO USE

It should be behind of the subject, fitted in the X-ray machine.



12. DEVICE DESCRIPTION

No	Contents	Description
1	Intended purpose (use)	This device (grid) is intended to reduce the amount of scattered radiation reaching the image receptor in order to make the image more precise and clear.
2	UDI code (GTIN 13 digits)	880 01922 0000 2 (Our grid is class I.)
3	Indications	Chest X-ray and fracture
4	Contra-indications	There is no contra-indication.
5	Patient target group(s) and intended users	Patients of Pulmonary tuberculosis and Fracture/ This device (grid) should be operated by the educated operator.
6	Warnings, cautions (e.g. for the direction and tube side of the grid)	<ul style="list-style-type: none"> * When taking X-ray, the operator can get a good image at optimal F.D. moving the tube up and down. * The operator should be careful not to drop the grid, when move it. * Grid can be damaged when the operator drops because of carelessness during transportation (moving or carrying).
7	Warnings or cautions to be taken into account with a view to the safe disposal of the product, its accessories and consumables, if used.	<ul style="list-style-type: none"> *This device should be operated by the educated operator. * Please pay attention to the sudden injury to the patient or operator by dropping this item when in use due to its heavy weight. *Actions taken to prevent nonconforming products from being used for their intended purpose
8	Side Effect	There is no side-effect.
9	Single use / reusable	It is not a single use device.
10	Sterility	It is not a sterile device.
11	Configurations of the product	One X-ray Grid wrapped with a polybag is in one outer box.
12	Whether it incorporates a medicinal substance (already on the market or new), animal tissues, or blood components, the purpose of the component	It does not incorporates a medicinal substance.

13. CAUTION IN USE

- . When taking X-ray, the operator can get a good image at optimal F.D. moving the tube up and down.
- . The operator should be careful not to drop the grid, when move it.
- . Should be operated this grid by educated operator only.
- . Storing condition : 40℃ ~ -25℃
- . Operating condition : normal room temperature 5 ~ 40℃
- . When damaged? Grid can be damaged when operator drops because of carelessness during transpotation (moving or carrying).
- . Please pay attention to the sudden injury to the patient or operator by dropping this item when in use due to its heavy weight.

Ambient temperature range

-operation : 5~40℃

-storing & transport : -25 ~40℃

Relative Humidity range

-operation : 20~80%

-storage & transport : 5~90%

14. TECHNICAL GUIDE

KV	filtration mm Al Equivalent
60-75	2
100-125	4

15. GRID PHOTO



16. Reference to the MDR regulation 2017/745

In accordance with **Regulation (EU) 2017/745** of the European Parliament and of the Council of 5 April 2017

We herewith declare that the under-mentioned products meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017. This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer. All supporting documentation is retained at the premises of the manufacturer. The device that is covered by the present declaration is in conformity with the **Regulation (EU) 2017/745**.

We declare that the X-Ray Grid (Criss-Cross Grid, Linear Parallel Grid, Linear Focused Grid) has been classified as Class I in accordance with the rule 1 of Classification Rules set out in Annex VIII of **Regulation (EU) 2017/745**

Products Name: Anti scattered radiographic grid (X-ray grid)

Model: Criss-Cross Grid, Linear Parallel Grid, Linear Focused Grid

Basic UDI-DI: 88001922SY5515633QP

GMDN CODE: Stationary x-ray grid, 40915

X-ray Grid (Criss-Cross Grid, Linear Parallel Grid, Linear Focused Grid) is in conformity with the harmonized standards EN ISO 15223-1:2016, EN 1041:2008, EN ISO 13485:2016, EN ISO 14971:2012, EN 60627:2015

Authorised Representative: CMC Medical Devices & Drugs S.L. C/Horacio Lengo Nº 18, CP 29006, Málaga, Spain

17. REMARKS

Unless somebody gives physical damage on it, it never be transformed and therefore, this product can be used 12 months as consumable. It should be kept away from the external physical power. When it is fitted in an X-ray machine, it may be safe unless somebody change it at his discretion.

<p>Manufacturer</p> <p>SOYEE PRODUCT INC.</p> <p>1909-2 KWTC 159-1</p> <p>Samsungdong, Kangnamku,</p> <p>Seoul, Korea</p> <p>Tel : 82 2 551 5631</p> <p>Fax : 82 2 551 5636</p> <p>E-mail : shk@soyee.co.kr</p>	<table border="1"><tr><td>EC</td><td>REP</td></tr><tr><td colspan="2">CMC Medical Devices & Drugs S.L.</td></tr><tr><td colspan="2">C/Horacio Lengo Nº 18, CP 29006,</td></tr><tr><td colspan="2">Málaga, Spain</td></tr><tr><td colspan="2">Tel.: +34 951 214 054</td></tr><tr><td>CH</td><td>REP</td></tr><tr><td colspan="2">CMC Medical Devices GmbH</td></tr><tr><td colspan="2">Bahnhofstrasse 32, CH-6300 Zug, Switzerland</td></tr></table>	EC	REP	CMC Medical Devices & Drugs S.L.		C/Horacio Lengo Nº 18, CP 29006,		Málaga, Spain		Tel.: +34 951 214 054		CH	REP	CMC Medical Devices GmbH		Bahnhofstrasse 32, CH-6300 Zug, Switzerland	
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