.decimal®

On Demand Design and Delivery of Custom Treatment Devices

Virtual Mold Room

"The Future of Custom Radiation Therapy Devices"

Safety | **Quality** | **Savings**

Virtual Mold Room

"The Future of Custom RT Devices"

Safety

- Lead (a component of cerrobend) is an OSHA regulated hazardous material.
- Accidental exposure to lead poses a health risk to patients and staff.
- The need for cerrobend in the clinic has fallen dramatically, but the requirements for regulatory compliance have increased.

Quality

- Common OSHA and State violations include:
  - Failure to record air monitoring
  - Failure to provide or utilize required Personal Protective Equipment
  - Failure to have written Hazardous Materials Procedures
  - Failure to implement or record Hazardous Materials Training Records for all employees
  - Failure to inform (in writing) employees of the harmful effects of lead exposure

Savings

- Eliminate health and regulatory risk with .decimal copper electron cut outs.

Virtual Mold Room

"The Future of Custom RT Devices"

Safety

Quality

Savings

- .decimal® is an FDA compliant manufacturer. All .decimal® devices have 510K approval.
- *.decimal® qualifications*:
  - Longevity - 30 years serving the radiation oncology community
  - Over 47,000 patients treated with .decimal® custom devices
  - Over 250,000 custom devices manufactured
  - ISO Certifications: 9001 (manufacturing); 14001 (medical device); 13485 (environmental)
  - Over 500 centers utilize .decimal custom devices across the US
- *Unparalleled accuracy*: All .decimal® devices are computer designed and precision milled or manufactured to meet your exact specifications.
- *Copper electron cut outs are better:*
  - Research shows the blocking power of copper is equal to that of cerrobend
  - Copper offers better protection to healthy tissue outside the treatment area
  - Copper eliminates regulatory risk associated with cerrobend cut outs

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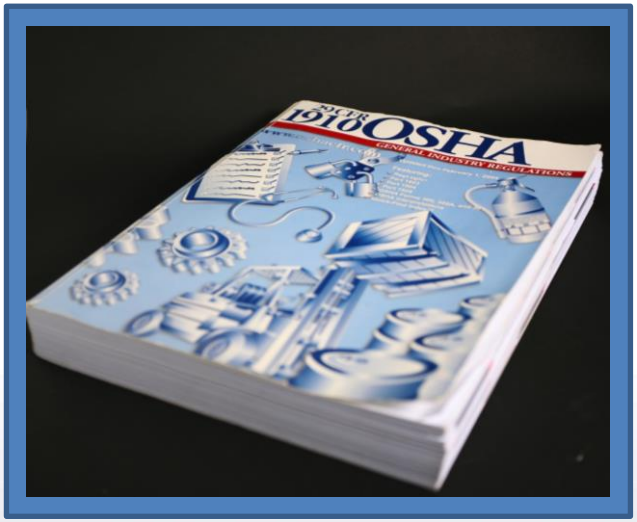
Safety

Quality

Savings

- Today, mold/block rooms are utilized primarily for electron treatments, usually only 5-10% of an average clinic's patient load.
- Regulatory compliance is expensive and requires valuable resources:
  - money
  - time
  - personnel
  - clinic space
- Non-compliance fines are even more expensive! Infractions are difficult to avoid and fines can total many thousands of dollars.
- Don't waste valuable resources on something that carries unnecessary risk and expense.

Small Sampling of OSHA Requirements



Procedures

- ❑ Written Hazardous Communications Procedures
- ❑ Hazardous Communication Training Records for all employees
- ❑ Written Hazardous Materials Procedures
- ❑ Hazardous Materials Training Records for all employees
- ❑ Written Hazardous Materials Disposal Plan
- ❑ Hazardous Materials Disposal Training Records for all employees

Facility

- ❑ Housekeeping
  - ❖ All surfaces shall be maintained free of accumulations of lead
  - ❖ Room kept clean to minimize reentry of lead into the workplace
  - ❖ Employer shall assure that food or beverage is not present or consumed
- ❑ Separation of Mold Room Area from Main Facility HVAC System
  - ❖ Separate Vacuum and Filtration Systems
  - ❖ Recirculation of air, employer shall assure the system has high efficiency filter with reliable back-up
- ❑ Mold Room Air Monitoring
  - ❖ Annually by qualified 3rd party inspection

Lead Testing

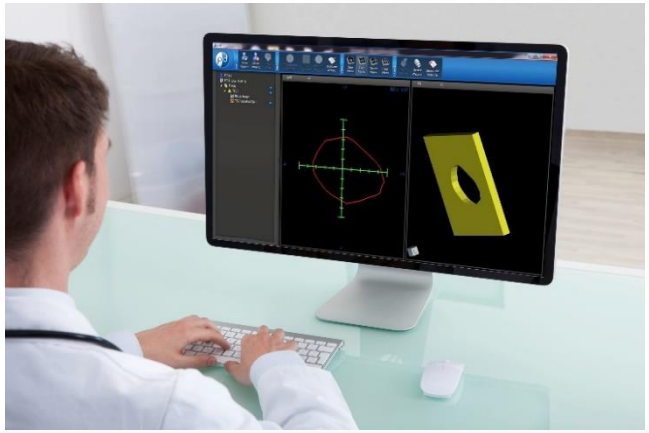
- ❑ Medical Surveillance of all employees exposed to lead more than 30 days per year
- ❑ Employee blood lead and ZZP level sampling and analysis annually
- ❑ Room Air Monitoring – Minimum annually based on results (for at least 7 continuous)
- ❑ Employee notification of air monitoring results and corrective actions if results exceed standard.

Other Issues with In-House Mold Rooms

- Human resources to fabricate the blocks
- Human resources and cost for equipment maintenance
- Human resources for regulatory compliance
- Maintaining inventory (styrofoam blocks, PPE, hazardous material cleaning supplies, etc)
- Chance for accidents (spills, cuts, burns)
- Variability of handmade blocks (varying staff skill, clinic to clinic variability, etc.)
- Tying up valuable clinic real estate for something seldom used.

Virtual Mold Room

Custom devices are designed at your clinic using your TPS and .decimal® p.d software



Device files are sent to .decimal® electronically for manufacturing

Devices are shipped FedEx overnight

Custom devices arrive at your clinic within 24 - 48 hours

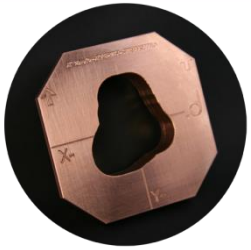
Conclusions

"Using custom milled copper inserts for electron beam therapy planned with standard commissioning data measured using Cerrobend inserts results in minimal in-field dosimetric differences (<2%) for standard clinical applicators (2x2-20x20 cm^2).

The largest dosimetric differences (>2%) result from the lower out-of-field dose for copper inserts due to a reduction in bremsstrahlung production as compared to Cerrobend. Clinically, this dosimetric difference is insignificant, as the use of copper inserts could reduce the dose received by healthy tissue outside of the planned treatment volume."

Full Research Poster (AAPM 2014) can be found at:

www.dotdecimal.com



Copper Cutout Cost / Recycle Value / Reimbursement

Cone Size	Cost	*Estimated Recycle Value
< 10 x 10	$115.00	$10 - $12
14 x 14	$144.00	$19 - $23
15 x 15	$144.00	$20 - $24
20 x 20	$230.00	$32 - $36
25 x 25	$288.00	$47 - $52
25 x 25 (Elekta)	$316.00	$47 - $52
*** Upon completion of patient treatment, recycle the copper locally**		
85+% of the orders we receive (since 2010) are 15 x 15 or smaller		

2022 Medicare Reimbursement National Average

CPT Code	Hospital-based	Free-standing
77334 Complex Device	$345.85	$125.97

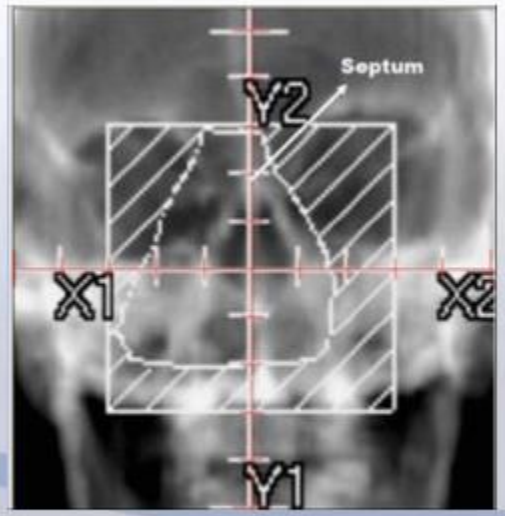
Prices does not include shipping cost. Shipping cost will vary based on weight, location of delivery, and shipping priority.

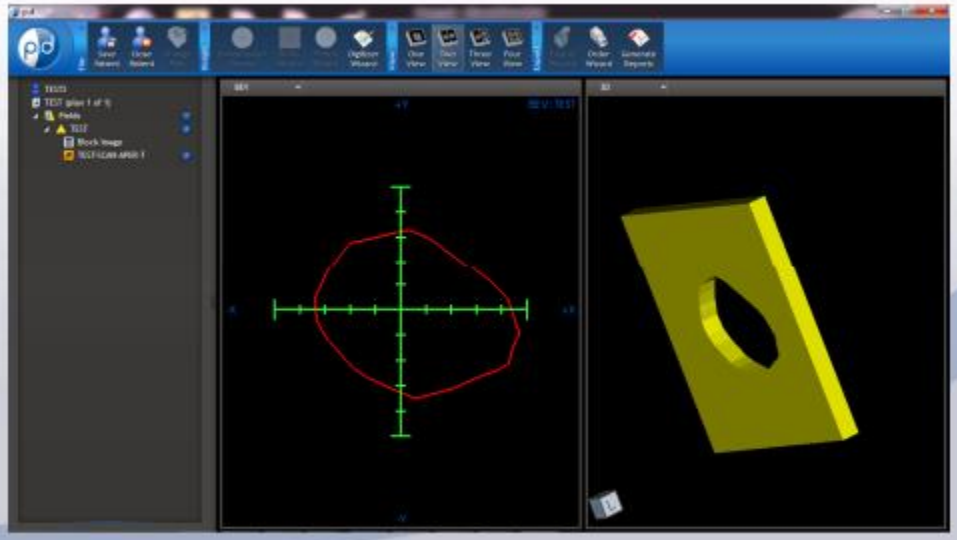
How to Order

- .decimal provides software for ordering
- Cut out files can be created two ways: in the TPS, or, by clinical set up.
- The following slides will illustrate both methods

Designed within TPS

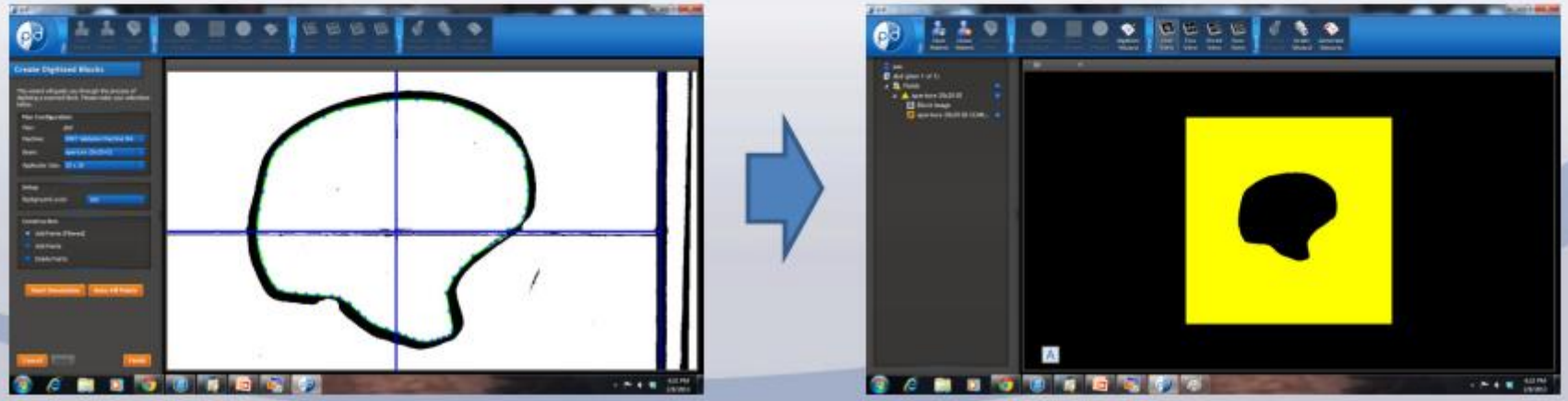
- Create aperture in planning system as usual
- DICOM RT export beam / aperture to .decimal p.d software





Clinical Set Up

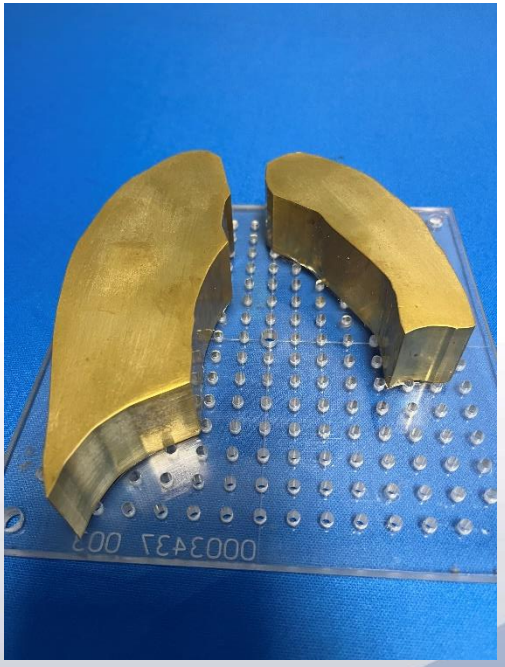
- Digitize drawing of opening
- Save digitized file



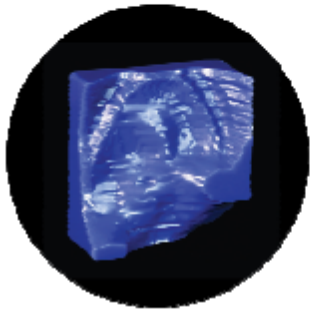
Total Body Irradiation (TBI)

- For centers that offer TBI, Decimal provides TBI blocks made from brass.
- Standard turnaround time is 2 business days for orders received by 3 PM EST.

Brass Size	Cost
2” Thick: Length < 4.5”	$300.00
2” Thick: Length 4.5” – 6.5”	$450.00
2” Thick: Length > 6.5”	$600.00
3” Thick	$600.00
Prices are for a single two-piece block set (left & right lung pair)	

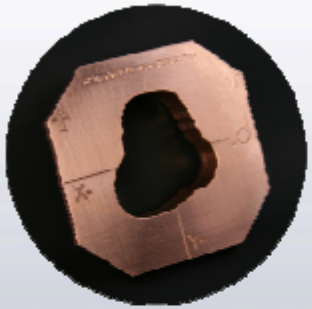


Client Testimonials:



"We use .decimal blocks, e- cutouts and bolus as they are wonderful tools for our physicians and staff. The blocks and e- cutouts have allowed us to confidently do away with our block room and the boluses have helped us on numerous challenging cases. The .decimal software is very user-friendly and accommodating for challenging and time sensitive cases."

~ AJ Carper, Medical Physicist, Midwestern Regional Cancer Center, Zion, IL



"We use .decimal for manufacturing of shield devices for electron beam therapy to eliminate the on-going safety requirements required by regulatory agencies, i.e Labor and Industries, Department of Health, and JCH. The service has been excellent…high quality, safe, shielding products. The precision cut of the devices are noticeably better than those we ever constructed…"

~ Sue Smiley, Manager-Radiation Oncology, Evergreen Health, Kirkland, WA

.decimal

On-demand design and delivery of custom, patient-specific treatment devices for cancer patients

The Future of Custom Devices – ***Today!***

.decimal®

On Demand Design and Delivery of Custom Treatment Devices

"The Future of Custom Radiation Therapy Devices"

Safety	Quality	Savings
No lead exposure to patients or staff	Computer designed and precision manufactured for 100% accuracy	No risk of fines for non-compliance (OSHA and other regulatory agencies)
No compliance headaches	Copper electron cuts outs are proven safe and effective	No costly mold room maintenance

Let .decimal® show you how to eliminate expense and risk!

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1.800.255.1613

For more details or a mold room compliance checklist visit:
www.dotdecimal.com